

Exhibit G

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March 31, 2023

Deputy Agency Chief FOIA Officer
Office of the Assistant Secretary for Public Affairs U.S. Department of Health and Human
Services Hubert H. Humphrey Building
200 Independence Avenue
Suite 729H
Washington, D.C. 20201
FOIARequest@psc.hhs.gov

Re: Fee Waiver Appeal of FOIA Request #23-00462-FOIA

Dear FOIA Officer:

I represent the non-profit organization Freedom Coalition of Doctors for Choice (hereafter “Freedom Coalition”). On January 3, 2023, on behalf of Freedom Coalition, I submitted a request for records (hereafter “FOIA Request”) from the files of the Centers for Disease Control and Prevention (hereafter “CDC”) pursuant to the Freedom of Information Act (hereafter “FOIA”). On January 4, 2023, CDC acknowledged the FOIA Request and denied Freedom Coalition’s fee waiver request. Freedom Coalition writes now to appeal this denial.

Background:

On January 3, 2023, Freedom Coalition submitted a request to CDC for the following documents:

All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).

(Attachment 1.)

As part of its request, Freedom Coalition requested that CDC waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government. Freedom Coalition detailed three ways the disclosure of the requested information would contribute to that understanding. It stated:

(1) the disclosure of the requested information will provide the public with primary source documentation of the reactions v-safe

participants experienced during regularly set intervals after receiving various doses of the COVID-19 vaccines originally approved under the government issued Emergency Use Authorization;(2) this data will shed light on the overall safety and efficacy of the COVID-19 vaccines for the over 10 million v-safe participants, a substantial sample size to synthesize important information regarding the vaccines' safety and efficacy; and

(3) the disclosure of the information described above will shed light on whether CDC and other health agencies appropriately monitored and acted upon the information provided by v-safe participants. The information the [Freedom Coalition] requests will not contribute to any commercial activities.

On January 4, 2023, CDC acknowledged the request, assigned it request number 23-00462-FOIA, and denied Freedom Coalition's request for a fee waiver stating in relevant part:

You requested that we waive fees associated with processing your request, your request is denied because it doesn't meet the following criteria:

- ☐ You have failed to demonstrate that you disseminate information to the public.
- ☐ You have failed to provide enough information to warrant a waiver of fees.

(Attachment 2.)

CDC issued a final response to the request on January 12, 2023, declaring "the agency is withholding the v-safe free-text-fields data." (Attachment 3.) Freedom Coalition submitted an appeal challenging the agency's withholding of responsive records, and the appeal was officially acknowledged on January 17, 2023. (Attachment 4.) Despite the passage of over 30 business days, CDC has failed to make any determination with respect to Freedom Coalition's appeal.

Argument:

CDC should waive any and all fees or charges associated with the processing of Freedom Coalition's FOIA Request because Freedom Coalition has sufficiently detailed how the requested information is in the public interest and likely to contribute significantly to the public understanding of the operations or activities of CDC. Additionally, even if it is determined Freedom Coalition is not entitled to a complete fee waiver, its status as an educational institution requester, or member of the media, entitles it to reduced fees and costs. Moreover, Freedom Coalition's entitled to reduced fees and costs because CDC failed to abide by the time limits of FOIA.

1. The requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government

Under FOIA, “[d]ocuments shall be furnished without any charge or [reduced] . . . if disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester. Furthermore, under FOIA, federal agencies are required to “promulgate regulations . . . specifying the schedule of fees applicable to the processing of requests . . . and establishing procedures and guidelines for determining when such fees should be waived or reduced.” 5 U.S.C. § 552(a)(4)(A)(i). The U.S. Department of Health and Human Services (“HHS”), CDC’s parent department, has promulgated regulations regarding fees and fee waivers applicable to FOIA Requests. 45 C.F.R. §§ 5.51 – 5.54.

HHS regulations provide that the agency “must furnish records responsive to a request without charge or at a reduced rate” if it determines that: (1) “[d]isclosure of the requested information would shed light on the operations or activities of the government”; (2) “[d]isclosure of the requested information would be likely to contribute significantly to public understanding of those operations or activities”; and (3) “[t]he disclosure must not be primarily in the commercial interest of the requester.” 45 C.F.R. § 5.54(b). All three factors are present here.

a. Disclosure of the requested information would shed light on the operations or activities of the government

The disclosure of the information Freedom Coalition has requested – all data from v-safe’s free-text fields – will shed light on the operations or activities of the government. As explained below, the relevant free-text entries provide the most critical and informative dataset available for assessing the safety and efficacy of the existing COVID-19 vaccines. Therefore, the disclosure of the information will shed light on whether CDC properly analyzed the information to detect and evaluate clinically important adverse events and safety issues that impacted its relevant policies or regulatory decisions and recommendations.

CDC claims that the current “COVID-19 vaccines are being administered under the most intensive vaccine safety monitoring effort in U.S. history[.]”¹ CDC also explained that its leading vaccine safety system, the Vaccine Adverse Events Reporting System (“VAERS”), was incapable of determining causation and was otherwise unreliable to assess the safety of COVID-19 vaccines. As a result, CDC deployed a new safety monitoring system for the COVID-19 vaccines: **v-safe**.

V-safe is CDC’s premier safety system for tracking the safety of COVID-19 vaccines. V-safe is an online software program, accessible through the use of a smart phone, that allows vaccine recipients to “tell CDC about any side effects after getting the COVID-19 vaccine.”² The purpose of the program, as explained by CDC, “is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important

¹ <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/05-COVID-Hause-508.pdf>.


² <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html>.

adverse events and safety issues that might impact policy or regulatory decisions.”³

V-safe collected COVID-19 vaccine safety information in two ways from its approximate 10 million users. The first is with check-the-box questions. The second is with free-text fields.

With regard to the check-the-box data collected, it is limited to two categories of information. The first asks v-safe users to select one or more of 10 symptoms that occurred within the first week after vaccination. For example, see the image below:

³ <https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf>.




v-safe
after vaccination
health checker

Dose 1 - Day 1-7


Hi Olivia,

Let's start today's health check-in.


How are you feeling today? *



Good



Fair



Poor

Fever Check

Have you had a fever or felt feverish TODAY? *

☒ Yes ☐ No

Do you know your highest temperature reading from today? *

☐ Yes - in degrees Fahrenheit
☐ Yes - in degrees Celsius
☐ No - I don't remember the reading
☒ No - I didn't take my temperature

Symptom Check

Since your COVID-19 Vaccination, have you had any of these symptoms at or near the injection site?

Select all that apply:

☐ Pain ☐ Redness ☐ Swelling ☐ Itching ☒ None

Have you experienced any of these symptoms today?

Select all that apply:

☐ Chills
☐ Headache
☐ Joint pains
☐ Muscle or body aches
☐ Fatigue or tiredness
☐ Nausea
☐ Vomiting
☐ Diarrhea
☐ Abdominal pain
☐ Rash, not including the immediate area around the injection site
☒ None

Any other symptoms or health conditions you want to report

Health Impact

Did any of the symptoms or health conditions you reported TODAY cause you to: *

Select all that apply:

☐ Be unable to work
☐ Be unable to do your normal daily activities
☒ Get care from a doctor or other healthcare professional
☐ None of the above

What type of healthcare visit did you have? *

☐ Telehealth, virtual health, or email health consultation
☐ Outpatient clinic or urgent care clinic visit
☐ Emergency room or emergency department visit
☒ Hospitalization

Other, please describe

Submit

This list of symptoms are the same symptoms CDC says are normal to occur after vaccination and are actually a sign the vaccine is working by producing an immune response.⁴ Therefore, for the assessment of the overall safety of COVID-19 vaccines, it was pointless to gather this information regarding these 10 symptoms.

The only other check-the-box safety information collected (other than symptoms) is asking v-safe users whether they needed medical care, missed school or work, or could not perform normal daily activities (the “**health impact data**”). If the user selected needing medical care, they were then asked to select whether they sought telehealth, urgent care, emergency care, or were hospitalized. The health impact data, unlike the check-the-box symptoms data, is collected beyond the first week after injection, and is collected weekly for the first six weeks after injection, then again at 3, 6 and 12 months.

While the collection of the health impact data is an important part of gaging the safety of the COVID-19 vaccines, the free-text fields provide the only opportunity for v-safe users to report more complex and serious adverse events that occurred after vaccination. For example, in the first version of the v-safe protocol, prior to its launch, CDC identified the following adverse events of special interest in a chart titled Prespecified Medical Conditions:

Attachment 2: Adverse Events of Special Interest

Prespecified Medical Conditions
Acute myocardial infarction
Anaphylaxis
Coagulopathy
COVID-19 Disease
Death*
Guillain-Barré syndrome
Kawasaki disease
Multisystem Inflammatory Syndrome in children ¹
Multisystem Inflammatory Syndrome in adults ²
Myocarditis/Pericarditis
Narcolepsy/Cataplexy
Pregnancy and Prespecified Conditions
Seizures/Convulsions
Stroke
Transverse Myelitis

* Capture of deaths through v-safe will be limited.

(Attachment 5.)

CDC also identified many of these adverse events as potential harms of concern from COVID-19

⁴ See <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html>; <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html>.

vaccines, in a presentation on October 30, 2020, titled “CDC post-authorization/post-licensure safety monitoring of COVID-19 vaccines.”⁵ Despite CDC itself directly identifying these adverse events as harms of potential concern, it did not include check-the-box options for users to report these harms, nor did it even provide any check-the-box options for common symptoms from these harms. Instead, CDC oddly purposely chose to limit reporting of any such adverse events to the free-text fields, a data collection method that is far more difficult to standardize and tabulate.

CDC had an obligation to properly review and tabulate the data to detect and evaluate clinically important adverse events and safety issues.⁶ Until this critical data obtained from these free-text fields is released to the public, there is no way for the public and scientific and medical community to determine whether CDC adequately acted upon *the most critical information it obtained from v-safe users*. In addition, the disclosure of this critical information will shed light on the legitimacy and reasonableness of the policy and regulatory decisions and recommendations CDC made with respect to the COVID-19 vaccines.

Therefore, the release of the requested information is in the public interest because it is likely to contribute significantly to the public’s understanding of the operations or activities of the government. Thus, the first factor weighs heavily in favor of granting Freedom Coalition a fee waiver.

b. Disclosure of the requested information would likely to contribute significantly to public understanding of governmental operations or activities

The disclosure of the data obtained from the free-text fields would significantly contribute to the public’s understanding of whether CDC properly analyzed the information to detect and evaluate clinically important adverse events and safety issues, and whether it implemented the correct policy or regulatory decisions based off the data it received. Currently, CDC claims it received 7.8 million free-text entries from v-safe users. (Attachment 3.) However, CDC has not allowed the public to assess the critically important data obtained from these free-text fields.

As explained in the section above, because of how CDC structured the v-safe program, these free-text entries provide the only opportunity to report serious adverse events in the v-safe system. Moreover, these free-text entries provide the most critical and informative dataset available for assessing the safety and efficacy of the existing COVID-19 vaccines because they were collected from a known sample size of participants directly reporting their symptoms and reactions. Thus, the rate at which an adverse event is reported can be calculated and relied upon. Therefore, the disclosure of the requested information would likely contribute significantly to public understanding behind the legitimacy of CDC’s numerous policy and regulatory decisions and recommendations based on its assertion that the COVID-19 vaccines are safe and serious adverse events are *statistically rare*.⁷

The numerous policy and regulatory decisions and recommendations CDC made regarding the COVID-19 vaccines played a major role in influencing large segments of society to mandate

⁵ <https://stacks.cdc.gov/view/cdc/97350> at 17.

⁶ <https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf>.

⁷ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html>.

the receipt of the COVID-19 vaccines. Largely because of these vaccine mandates, more than 265 million Americans received at least one COVID-19 vaccine.⁸ Therefore, a large segment of the public would likely be interested in learning the rates of serious adverse events that were reported in v-safe, CDC's premier safety system for tracking the safety of COVID-19 vaccine.

Freedom Coalition is in a unique position to facilitate the review, analysis, and dissemination of the information it receives from this request. Freedom Coalition is a nonprofit organization that exists for the sole purpose of obtaining and disseminating to the public the data from the free-text fields in CDC's v-safe database. The coalition is made up of medical and public health professionals, scientists, and journalists. It takes no position on this data other than that it should be made available to the public and scientific community as soon as possible. All data obtained will be made available on its website, www.drsgforchoice.org, upon receipt. Its network of uniquely qualified members and supporters will enable the information obtained from this request to be easily and meaningfully distributed to wide segment of the American public.

Therefore, the disclosure of the requested information would likely contribute significantly to public understanding of CDC's operations and activities. Thus, the second factor weighs heavily in favor of granting Freedom Coalition a fee waiver.

c. The disclosure is not primarily in the commercial interest of the requester

The information Freedom Coalition seeks is not "primarily in the commercial interest of the requester." The disclosure of records from this request will not contribute to any commercial activities. Freedom Coalition is a non-profit that exists for the sole purpose of obtaining and disseminating to the public the data from the free-text fields in CDC's v-safe database. (Attachment 6.) It fully intends to disseminate the disclosed information for free and will not profit from the disclosure of the requested information. Thus, the third factor weighs heavily in favor of granting Freedom Coalition a fee waiver.

Freedom Coalition has established all the criteria HHS and CDC find necessary to furnish records without charge, therefore the fee waiver request should be granted. 45 C.F.R. § 5.54(b).

2. Freedom Coalition is not an "Other Requester"

Even if CDC determines a full fee waiver is not appropriate, Freedom Coalition should be considered an educational institution requester, or a member of the media. As explained above, Freedom Coalition is a nonprofit that exists for the sole purpose of obtaining and disseminating to the public the data from the free-text fields in CDC's v-safe database.⁹ It intends to provide access to the disclosed data to the public for free through its website, and its network of members and supporters which includes medical personnel and journalists. Therefore, at the very least, Freedom Coalition is "entitled to search time, review time, and up to 100 pages of duplication (or the cost equivalent for other media) without charge." 45 U.S.C. § 5.53(b).

⁸ <https://www.nytimes.com/interactive/2020/us/covid-19-vaccine-doses.html>.

⁹ <https://www.drsgforchoice.org/>.

3. CDC is required to waive fees when it fails to abide by the time limits of FOIA.

CDC should waive or reduce fees because it failed to make a determination with respect to Freedom Coalition's appeal within the time limits prescribed by FOIA. An agency must make a determination with respect to a requester's appeal within 20 business days of its receipt. 5 U.S.C. § 522(a)(6)(A)(ii). If the agency provides an adequate notice of "unusual circumstances" the deadline for the agency's determination can be extended to a total of 30 business days. 5 U.S.C. § 522(a)(6)(B)(i). When an agency fails to comply with these deadlines "and agency shall not assess any search fees [or duplications fees]." 5 U.S.C. § 522 (a)(4)(A)(viii)(I). Even when unusual circumstances apply and more than 5,000 pages are necessary to respond to the request, an agency may not charge search or duplications fees unless the agency has discussed with the requester how it could effectively limit the scope of the request. 5 U.S.C. § 522(a)(4)(A)(viii)(II).

In this instance, CDC failed to make a determination with respect to Freedom Coalition's appeal within 30 days. Furthermore, CDC never discussed with Freedom Coalition how it could effectively limit the scope of the request. Therefore, Freedom Coalition should not have to pay all the fees CDC incurs or incurred during the processing of its request. 5 U.S.C. § 522(a)(4)(A)(viii)(I); 5 U.S.C. § 522(a)(4)(A)(viii)(II).

Appellate Request

For all the reasons detailed above, Freedom Coalition appeals CDC's fee waiver denial and requests the agency make a determination with respect to this fee waiver appeal in 20 days as FOIA requires. Thank you for your time and consideration into this matter. If you have any questions regarding this appeal, please feel free to contact me at Chris@cwiestlaw.com or 513-257-1895.

Regards,

/s Christopher Wiest

Christopher Wiest

Attachment 1

Attachment 1

Submit New Request

23-00462-FOIA

Requester Details

To modify request details please update your requester profile or contact the our office for assistance.

Christopher Wiest

Attorney

Chris Wiest, Attorney at Law, PLLC

5 Town Center Blvd

Ste. 104

Crestview Hills, KY 41017

Phone 5132571895

Email chris@cwiestlaw.com

Requester Default Category: All Others

General Information

Location Office	HQ
Location Office Instructions	CDC/ATSDR FOIA Office 1600 Clifton Road, N.E., MS D-54 Atlanta, Georgia 30152
Request Type	FOIA
Requester Category	Non-Commercial Scientific
Delivery Mode	E-mail

Shipping Address

Street1	25 Town Center Blvd
Street2	Ste. 104
City	Crestview Hills
State	Kentucky
State (Other)	
Country	United States
Zip Code	41017

Request Information

Description	All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).
Date Range for Record Search:From	10/01/2020
Date Range for Record Search:To	12/31/2022
Description Document	CDC v-safe free text request.pdf

Fee Information

Billing Amount	\$25
Fee Waiver Requested	Yes ,CDC v-safe free text request.pdf
Fee Waiver Request Reason	See attached.
Willing to Pay All Fees	No

Billing Address

Street1	25 Town Center Blvd
Street2	Ste. 104
City	Crestview Hills

Other Information

lame
ompany
hone
ax
mail Address
treet1
treet2
ity
tate
tate (Other)
ountry
ip Code

25 Town Center Blvd
Ste. 104
Crestview Hills
Kentucky

United States
41017

Expedite Information

Expedite Reason

See attached.

January 3, 2023

Freedom of Information Officer
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Building 57, Room MS D-54
Atlanta, Georgia 30333

RE: Expedited Processing Requested for Accompanying Freedom of Information Act (FOIA)
Request for V-Safe's Free Text Fields

Dear FOIA Officer,

I am writing on behalf of the non-profit organization Freedom Coalition of Doctors for Choice ("**Organization**") and its members. Pursuant to the Freedom of Information Act ("**FOIA**"), the members of this organization would like CDC to provide the following records in an expedited manner and in electronic form: **All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).**

Freedom Coalition of Doctors for Choice is a nonprofit and asks that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that "disclosure of the [requested] information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government[.]" The disclosure of the requested information will contribute to the public's understanding in at least three ways: (1) the disclosure of the requested information will provide the public with primary source documentation of the reactions v-safe participants experienced during regularly set intervals after receiving various doses of the COVID-19 vaccines originally approved under the government issued Emergency Use Authorization; (2) this data will shed light on the overall safety and efficacy of the COVID-19 vaccines for the over 10 million v-safe participants, a substantial sample size to synthesize important information regarding the vaccines' safety and efficacy; and (3) the disclosure of the information described above will shed light on whether CDC and other health agencies appropriately monitored and acted upon the information provided by v-safe participants. The information the Organization requests will not contribute to any commercial activities.

Furthermore, the Organization also requests CDC provide expedited processing for this request. The information requested concerns matters of urgent public concern. The Organization's request for expedited processing should be granted because it qualifies under the "compelling need" analysis, as defined by FOIA. FOIA provides for "expedited processing of requests for records" upon a showing of a "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(I). A requestor shows a "compelling need" when it is (1) "primarily engaged in disseminating information," and (2) there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II). This request demonstrates both requirements below:

The requester is primarily engaged in disseminating information

The Freedom Coalition of Doctors for Choice is a not-for-profit organization that exists for the sole purpose of obtaining and disseminating to the public the free-text fields in the CDC's v-safe database. It is made up of medical and public health professionals, scientists, and journalists. Many of these individuals individually share with the public their findings, research, and professional opinions about Covid-19 and related issues. The coalition itself takes no position on this data other than that it should be made available to the public and the scientific community as soon as possible. It pledges that all data obtained from this request will be made available on its website – drsforchoice.org – upon receipt.

There is an urgency to inform the public concerning actual or alleged Federal Government activity.

In determining whether there is an “urgency to inform,” and hence a “compelling need,” courts must consider at least three factors: (1) whether the request concerns a matter of current exigency to the American public; (2) whether the consequences of delaying a response would compromise a significant recognized interest; and (3) whether the request concerns Federal Government activity. *Al-Fayed v. CIA*, 254 F.3d 300, 310 (D.C. Cir. 2001). All three factors are present here and weigh in favor of granting expedited processing of the Organization's FOIA request.

CDC is the federal agency responsible for administering and monitoring the v-safe program. CDC's website describes v-safe as an internet-based program that allows participants to “tell CDC how you, or your dependent, feel after getting any dose of COVID-19 vaccine.”¹ One of the purposes of the program “is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions.”² A major source of information CDC could use to detect and evaluate clinically important adverse events and safety issues was the data obtained from v-safe users/registrants, generated from the free text questions and responses within the v-safe program – the same information the Organization seeks in this request.

The contents of the information sought by this request could be analyzed and synthesized in meaningful ways to enable the public to better understand the potential benefits and risks involved in taking COVID-19 vaccines – or as the CDC currently recommends to all people ages 5 years and older – the COVID-19 vaccine booster.³ Without this information, which the CDC currently possesses but has not disclosed, the public is missing critical primary source information regarding v-safe participants' experiences taking the COVID-19 vaccines and the recommended boosters. Preventing the public and the scientific community from immediately accessing,

¹ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html>.

² <https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf>.

³ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html>.

analyzing, and synthesizing this information compromises the public's significant recognized interest of informed consent.⁴

The information sought is more urgent than ever because the federal government has recently implemented policies and messaging campaigns in order to promote the public's consent and access to the COVID-19 vaccines and boosters. However, to derive the public's informed consent, the federal government has an obligation to balance its messaging with – at the very least – access to the information it possesses regarding the possible risks and harms from receiving these medical products.

For example, transparency is even more critical now that the Advisory Committee on Immunization Practices (ACIP) has voted to add the COVID-19 vaccines to the routine childhood immunization schedule.⁵ This new policy may very likely cause states to create policies that grant or restrict certain privileges, such as attending school, based upon a child's COVID-19 vaccination status. Without disclosure, parents who are confronted with COVID-19 vaccine mandates are forced to choose between allowing their children to receive a vaccine without all the information available to make an informed decision, or their child being prevented from receiving an education based upon their vaccination status. Therefore, no matter a parent's choice when confronted with a COVID-19 vaccine mandate, a delay in the disclosure of the information sought in this request would compromise the public's significant recognized interest of informed consent.

As another example, the Biden administration has recently launched a major messaging campaign to increase the public's interest in receiving COVID-19 boosters.⁶ With the Biden administration's "new push to encourage families to get the updated COVID-19 vaccine" which includes "vaccination events" at "Head Start provider locations" under HHS' "#VaxUpAmerica Family Vaccine Tour," it is critical that the public has the latest information regarding possible signals of adverse reactions from these vaccines.⁷ Any delay in the processing of the request would deny families the information they need to provide their informed consent to the external pressures and messaging resulting from the current administration's actions.

Therefore, as demonstrated above, the Organization has shown (1) it is primarily engaged in disseminating information, and (2) there is an urgency to inform the public concerning actual or alleged Federal Government activities. Thus, the Organization's request for expedited processing should be granted.

⁴ Notions of informed consent have been codified in jurisdictions across the United States. For example, in Texas, a "recovery may be obtained [when there is] negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent." Tex. Civ. Prac. & Rem. Code § 74.101. Similarly, in New York, "informed consent shall include as a minimum, the specific procedure or treatment or both, their reasons for it, the reasonably foreseeable risks and benefits involved, and the alternatives for care or treatment, if any" 10 NYCRR § 405.7 (b)(9).

⁵ <https://www.aha.org/news/headline/2022-10-21-acip-recommends-adding-covid-19-vaccine-information-immunization-schedules>.

⁶ <https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/25/fact-sheet-president-biden-to-announce-additional-efforts-to-help-americans-get-their-free-updated-covid-19-vaccine-this-fall/>.

⁷ *Id.*

CDC's records are subject to disclosure under FOIA and are not otherwise exempt from disclosure pursuant to FOIA's nine statutory exemptions. To the extent that a determination is made by CDC that any limited portions of the records described above will be withheld from disclosure for this request, the Organization requests that the CDC segregate and disclose any portions of the records that are not exempt. Please expressly identify any exempt responsive records (or portions thereof) and the applicable FOIA exemptions for any responsive materials withheld for this FOIA request.

Our organization also requests that the agency provide an estimated date of completion for this request. Please inform me in writing if there are any "unusual circumstances" that will cause delay in responding to this FOIA request or providing the records which are requested.

If you have any questions regarding this FOIA request, please feel free to contact me at Chris@cwiestlaw.com or 513-257-1895.

Thank you in advance for your assistance in processing this request.

Regards,

/s Christopher Wiest
Christopher Wiest

Attachment 2



Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

January 4, 2023

SENT VIA EMAIL

Christopher Wiest
Attorney at Law, PLLC
25 Town Center Blvd Suite 104
Crestview Hills, Kentucky 41017
Via email: chris@cwiestlaw.com

Dear Mr. Wiest:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your Freedom of Information Act (FOIA) request dated January 3, 2023. Your request assigned number is 23-00462-FOIA, and it has been placed in our complex processing queue (copy enclosed).

Extension of Time

In unusual circumstances, an agency can extend the twenty-working-day limit to respond to a FOIA request.

We will require more than thirty working days to respond to your request because:

- ☐ We reasonably expect to receive and review voluminous records in response to your request.
- ☐ We reasonably expect to consult with two or more C/I/O/s, or another HHS operating division or another federal agency about your request.

To process your request promptly, please consider narrowing the scope of your request to limit the number of responsive records. If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, you may contact the analyst handling your request Irma S. Diaz at 770-488-6310 or our FOIA Public Liaison, Roger Andoh at 770-488-6277. Additionally, you may contact the Office of Government Services (OGIS) to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services; National Archives and Records Administration; 8601 Adelphi Road-OGIS; College Park, Maryland 20740-6001; e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

Expedited Processing

You requested that we expedite processing your request. Your request is denied because:

- ☐ You have failed to show that there is an imminent threat to the life or physical safety of an individual.
- ☐ You have not demonstrated that you are a person primarily engaged in disseminating information.

Fees and Fee Waivers

You requested that we waive fees associated with processing your request, your request is denied because it doesn't meet the following criteria:

- ☐ You have failed to demonstrate that you disseminate information to the public.
- ☐ You have failed to provide enough information to warrant a waiver of fees.

Fee Category

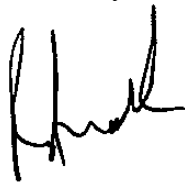
Because you are considered an "Other requester" you are entitled to two hours of free search time, and up to 100 pages of duplication (or the cost equivalent of other media) without charge, and you will not be charged for review time. We may charge for search time beyond the first two hours and for duplication beyond the first 100 pages. (10 cents/page).

Appeal Rights

You have the right to appeal the agency's expedited processing and fee waiver response to your request. You may file your appeal with the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, via the online portal at <https://requests.publiclink.hhs.gov/App/Index.aspx>. Your appeal must be electronically transmitted by April 5, 2023

You may check on the status of your case on our FOIA webpage <https://foia.cdc.gov/app/Home.aspx> and entering your assigned request number. If you have any questions regarding your request, please contact me at 770-488-6310 or via email at jyo0@cdc.gov.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
Phone: (770) 488-6399
Fax: (404) 235-1852

Attachment 3

Chris Wiest, Attorney at Law, PLLC

25 Town Center Blvd, STE 104
Crestview Hills, KY 41017
(513)257-1895 (cellular)
chris@cwiestlaw.com
*admitted in Kentucky and Ohio

January 13, 2023

Deputy Agency Chief FOIA Officer
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue
Suite 729H
Washington, D.C. 20201
FOIARequest@psc.hhs.gov

Re: *Appeal of FOIA Request #23-00462-FOIA*

Dear FOIA Officer:

I represent the non-profit organization Freedom Coalition of Doctors for Choice (hereafter “Organization”). On January 3, 2023, I submitted on behalf of the Organization a request for records (hereafter “FOIA Request”) from the files of the Centers for Disease Control and Prevention (hereafter “CDC”) pursuant to the Freedom of Information Act (hereafter “FOIA”). On January 12, 2023, CDC responded to the FOIA Request (hereafter “Final Response”). The Organization writes now to appeal the Final Response.

Background:

On January 3, 2023, the Organization submitted a request to CDC for the following documents:

All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).

(Attachment 1.)

On January 12, 2023, CDC issued a Final Response letter which stated in relevant part:

Please be informed that the agency is withholding the v-safe free-text-fields data for the following reasons:

- *There are 7.8 million free-text field entries collected in v-safe from registered users that contain personal identifiable information (PII).*
- *The agency lacks the resources to manually review the data collected from these registrants.*

Alternatively, we are providing you with a copy of the “v-safe motivation survey” dataset. This dataset includes survey responses collected from v-safe participants from May 1, 2022, through June 31, 2022. After a careful review, some of the information has been withheld from release pursuant to FOIA Exemption 6.

(Attachment 2.)

Argument:

CDC’s withholding of the requested free text fields (hereafter “requested records”) violates FOIA in two ways. First, CDC has failed to provide any exemption to justify withholding the requested records and a proper final ‘determination.’ Secondly, even if it has determined that portions of the requested records are not reasonably segregable, and they contain information relevant to protected privacy interests under Exemption 6, CDC has failed to demonstrate whether such privacy interests outweigh the public’s interest in disclosure.

1. CDC failed to provide a FOIA Exemption or sufficient reasoning for withholding records.

CDC unlawfully withheld records without invoking a FOIA Exemption and did not provide the Organization with an adequate ‘determination’ as required under FOIA. When the sufficiency of “the release of information under the FOIA” is challenged, “the agency has the burden of showing that requested information comes within a FOIA exemption.” *Pub. Citizen Health Research Grp. v. FDA*, 185 F.3d 898, 904, (D.C. Cir. 1999). An agency withholding responsive documents from a [FOIA] release bears the burden of proving the applicability of the claimed exemptions.” *American Civil Liberties Union v. DOD*, 628 F.3d 612, 619 (D.C. Cir. 2011).

“[I]n order to make a ‘determination’ and thereby trigger the administrative exhaustion requirement, the agency must at least: (i) gather and review the documents; (ii) determine and communicate the scope of the documents it intends to produce and withhold, and *the reasons for withholding any documents*; and (iii) inform the requester that it can appeal whatever portion of the ‘determination’ is adverse.” *Citizens for Responsibility & Ethics in Wash. v. FEC*, 711 F.3d 180, 188-89 (D.C. Cir. 2013) (Emphasis added); *see also* 5 U.S.C. § 552(a)(6)(A)(i) (“notify the person making such request of such determination *and reasons therefor*.”). “The statutory requirement that the agency provide ‘the reasons’ for its ‘determination’ strongly suggests that the reasons are particularized to the ‘determination’ — most obviously, the specific exemptions that may apply to certain withheld records.” *Citizens for Responsibility & Ethics in Wash.*, 711 F.3d at 186; *see also Khine v. United States Dep’t of Homeland Sec.*, 943 F.3d 959, 967-968 (D.C. Cir. 2019) (Court held the agency “satisfied its obligation to ‘determine and communicate . . . the reasons for withholding any documents’ because they “provided reasons by listing and defining the exemptions that the agency applied to the records” withheld.) Such reasonings need to incorporate a FOIA exemption in order to satisfy the agency’s obligations under FOIA. *Khine*, 943 F.3d at 967-968.

In this instance, CDC’s Final Response did not provide the information necessary to justify its reasoning for withholding records. CDC’s Final Response declares “the agency is withholding the v-safe free-text-fields data” but never details the applicable FOIA Exemption that justify its withholding. (See Attachment 2). CDC claims all “7.8 million free-text field entries collected from registered users . . . contain personal identifiable information (PII).” *Id.* CDC further claims

that it “lacks the resources to manually review the data collected from these registrants.” First, if CDC does not have the resources to manually review the free text fields, how does it know all 7.8 million free text entries contain PII. It does not adequately prove this assertion. Second, CDC has not provided any information on whether most – if not all – the PII can be removed through more automated mechanisms, as opposed to only “manual[] review.” For example, Social Security numbers, birthdates, phone numbers, registrant numbers, city names, etc. can likely be redacted through automated mechanism, or at least this information could be flagged for relatively easy manual redactions. Furthermore, if the free text fields are represented in a standardized template, and the PII is routinely detailed in certain boxes or locations in the template, the agency can automate a redaction overlay, that redacts these PII locations on every record. Therefore, CDC has not provided sufficient reasoning to withhold the requested records. For all the reasons described above, CDC has failed to justify withholding the requested records and provide the Organization with a sufficient final ‘determination.’ *Citizens for Responsibility & Ethics in Wash.*, 711 F.3d 188-89.

2. CDC failed to demonstrate that any unreasonably segregable portions of the requested records contain protected privacy interests that outweigh the public’s interest under Exemption 6.

Even if CDC could demonstrate that the unreasonably segregable portions of the requested records contain protected privacy interests, CDC has failed to demonstrate those interests outweigh the public’s interests in the requested records. “An agency withholding responsive documents from a FOIA request bears the burden of proving the applicability of the claimed exemptions.” *American Civil Liberties Union*, 628 F.3d at 619. Exemption 6 applies to prevent disclosure of “personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.” 5 U.S.C. § 552(b)(6). When evaluating withholdings under Exemption 6, there is a “presumption in favor of disclosure [that] is as strong as can be found anywhere in the Act.” *Multi AG Media LLC v. U.S. Dep’t of Agric.*, 515 F.3d 1224, 1227 (D.C. Cir. 2008) (quoting *Nat’l Ass’n of Homebuilders v. Norton*, 309 F.3d 26, 32 (D.C. Cir. 2002)) (internal quotation marks omitted). Therefore, an agency may withhold personal information only if “disclosure would compromise a substantial, as opposed to a de minimis, privacy interest.” *Nat’l Ass’n of Retired Fed. Emps. v. Horner*, 879 F.2d 873, 875 (D.C. Cir. 1989).

Furthermore, even when a privacy interests exist, courts must “weigh the privacy interest in non-disclosure against the public interest in the release of the records in order to determine whether, on balance, the disclosure would work a clearly unwarranted invasion of privacy.” *Lepelletier v. FDIC*, 164 F.3d 37, 46 (D.C. Cir. 1999) (internal quotation marks omitted); *see also U.S. Dep’t of State v. Washington Post Co.*, 456 U.S. 595, 598 (1982).

In this instance, CDC’s Final Response makes no indication whether the release of the information it has proven cannot be reasonably segregated would cause a “clearly unwarranted invasion of privacy.” *Lepelletier*, 164 F.3d 46. FOIA does not flatly prohibit the release of personal information that could cause an invasion of privacy. It only protects the release of personal information that would cause a clearly unwarranted invasion of privacy. Thus, the determination on whether an invasion of privacy is clearly warranted or not depends on the

public's interest and benefit in obtaining the released material. *Id.* In this case, the requested information the Organization seeks has insurmountable importance to the public, and yet CDC's Final Response provides no indication whether the public's interest in the requested records was even considered.

In consideration of this appeal, as CDC goes back to balance the privacy interests in non-disclosure versus the public's interest in disclosure, Organization provides the following information to emphasize the insurmountable public interest in the requested records:

CDC is the federal agency responsible for administering and monitoring the v-safe program. CDC's website describes v-safe as an internet-based program that allows participants to "tell CDC how you, or your dependent, feel after getting any dose of COVID-19 vaccine."¹ One of the purposes of the program "is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions."² A major source of information CDC could use to detect and evaluate clinically important adverse events and safety issues was the data obtained from v-safe users generated from the free text questions and responses within the v-safe program – the same information the Organization seeks in this request.

The contents of the information sought by this request could be analyzed and synthesized in meaningful ways to enable the public to better understand the potential benefits and risks involved in taking COVID-19 vaccines – or as CDC currently recommends to all people ages 5 years and older – the COVID-19 vaccine booster.³ Without this information, which CDC currently possesses but is refusing to disclose, the public is missing critical primary source information regarding v-safe participants' experiences taking the COVID-19 vaccines and the recommended boosters.

Failure to disclose this information prevents the public and the scientific community from immediately accessing, analyzing, and synthesizing critical safety information. This would compromise the public's significant recognized interest of informed consent, their ability to assess potential harms, develop strategies to prevent such harms, and treating those who have already been harmed.⁴ That is, for example, the core mission of React-19, a non-profit comprised of many individuals, and medical professionals, seriously injured from COVID-19 vaccines.

The members of React-19 are desperately seeking reliable data that can help explain the harms they are seeing among their members, currently only being observed in a non-systematic

¹ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html>.

² <https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf>.

³ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html>.

⁴ Notions of informed consent have been codified in jurisdictions across the United States. For example, in Texas, a "recovery may be obtained [when there is] negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent." Tex. Civ. Prac. & Rem. Code § 74.101. Similarly, in New York, "informed consent shall include as a minimum, the specific procedure or treatment or both, their reasons for it, the reasonably foreseeable risks and benefits involved, and the alternatives for care or treatments, if any . . ." 10NYCRR § 405.7 (b)(9).

fashion. Consequently, until these harms can be scientifically established through systematic datasets, the medical health establishment (including NIH, universities, etc.) will not fund research to address these harms and insurance companies will not pay for potential treatments. Moreover, irrespective of how many people complain of the harms – even if there are tens of thousands – without systematic datasets, influential segments of the medical health establishment consider these complaints as merely anecdotal. Therefore, these harms are allowed to continue dangerously unabated. The information derived from the free text fields can help provide information to alleviate some of these issues.

The information sought is indeed more urgent than ever because the federal government has recently implemented policies and a multi-billion-dollar messaging campaign in order to promote the public's uptake of the COVID-19 vaccines and boosters. However, as it promotes these products to obtain the public's consent to receive them, the federal government has an obligation to at least be transparent with the information it possesses regarding the possible risks and harms from receiving these medical products. This is made even more acute by the fact that the federal government has given nearly everyone immunity from liability for injuries caused by these products. Those who are injured by these products are left with virtually no recourse to obtain compensation. Therefore, the very least the government can do for consumers is to be transparent about the safety data. This transparency will allow consumers to make the most informed decision as possible, and will enable the medical and scientific community to assess ways to avoid and treat some of the harms currently being observed.

Transparency is even more critical now that the Advisory Committee on Immunization Practices (ACIP) has voted to add the COVID-19 vaccines to the routine childhood immunization schedule.⁵ This new policy may very likely cause states to create policies that grant or restrict certain privileges, such as attending school based upon a child's COVID-19 vaccination status. Without disclosure, parents who are confronted with COVID-19 vaccine mandates are forced to choose between allowing their children to receive a vaccine without all the information available to make an informed decision, or their child being prevented from receiving an education based upon their vaccination status. Therefore, no matter a parent's choice when confronted with a COVID-19 vaccine mandate, a delay in the disclosure of the information sought in this request would compromise the public's significant recognized interest of informed consent.

Furthermore, the Biden administration has recently launched a major messaging campaign to increase the public's interest in receiving COVID-19 boosters.⁶ With the Biden administration's "new push to encourage families to get the updated COVID-19 vaccine" which includes "vaccination events" at "Head Start provider locations" under HHS' "#VaxUpAmerica Family Vaccine Tour," it is critical that the public has the latest information regarding possible signals of adverse reactions from these vaccines.⁷ The refusal to disclose the requested records would deny families the information they need to provide their informed consent to the external pressures and

⁵ <https://www.aha.org/news/headline/2022-10-21-acip-recommends-adding-covid-19-vaccine-information-immunization-schedules>.

⁶ <https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/25/fact-sheet-president-biden-to-announce-additional-efforts-to-help-americans-get-their-free-updated-covid-19-vaccine-this-fall/>.

⁷ *Id.*

messaging resulting from the current administration's actions.

Lastly, if the requested information is disclosed, the Organization will, and has the capacity to make the information immediately available to the public. The Organization is a not-for-profit organization that exists for the sole purpose of obtaining and disseminating to the public the free text fields in CDC's v-safe database. It is made up of medical and public health professionals, scientists, and journalists. Many of these individuals individually share with the public their findings, research, and professional opinions about COVID-19 and related issues. The coalition itself takes no position on this data other than that it should be made available to the public and the scientific community as soon as possible. It pledges that all data obtained from this request will be made available on its website – drsforchoice.org – upon receipt.

Appellate Request:

For all the reasons detailed above, the Freedom Coalition of Doctors for Choice appeals CDC's Final Response and requests the agency make a determination with respect to this appeal in 20 days as FOIA requires. Thank you for your time and consideration into this matter. If you have any questions regarding this appeal, please feel free to contact me at Chris@cwiestlaw.com or 513-257-1895.

Regards,

/s Christopher Wiest
Christopher Wiest

Attachment 1

Submit New Request

23-00462-FOIA

Requester Details

To modify request details please update your requester profile or contact the our office for assistance.

Christopher Wiest

Attorney

Chris Wiest, Attorney at Law, PLLC

5 Town Center Blvd

Ste. 104

Crestview Hills, KY 41017

Phone 5132571895

Email chris@cwiestlaw.com

Requester Default Category: All Others

General Information

Location Office	HQ
Location Office Instructions	CDC/ATSDR FOIA Office 1600 Clifton Road, N.E., MS D-54 Atlanta, Georgia 30152
Request Type	FOIA
Requester Category	Non-Commercial Scientific
Delivery Mode	E-mail

Shipping Address

Street1	25 Town Center Blvd
Street2	Ste. 104
City	Crestview Hills
State	Kentucky
State (Other)	
Country	United States
Zip Code	41017

Request Information

Description	All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).
Date Range for Record Search:From	10/01/2020
Date Range for Record Search:To	12/31/2022
Description Document	CDC v-safe free text request.pdf

Fee Information

Billing Amount	\$25
Fee Waiver Requested	Yes ,CDC v-safe free text request.pdf
Fee Waiver Request Reason	See attached.
Willing to Pay All Fees	No

Billing Address

Street1	25 Town Center Blvd
Street2	Ste. 104
City	Crestview Hills

Other Information

lame
ompany
hone
ax
mail Address
treet1
treet2
ity
tate
tate (Other)
ountry
ip Code

25 Town Center Blvd
Ste. 104
Crestview Hills
Kentucky

United States
41017

Expedite Information

Expedite Reason

See attached.

January 3, 2023

Freedom of Information Officer
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Building 57, Room MS D-54
Atlanta, Georgia 30333

RE: Expedited Processing Requested for Accompanying Freedom of Information Act (FOIA)
Request for V-Safe's Free Text Fields

Dear FOIA Officer,

I am writing on behalf of the non-profit organization Freedom Coalition of Doctors for Choice ("**Organization**") and its members. Pursuant to the Freedom of Information Act ("**FOIA**"), the members of this organization would like CDC to provide the following records in an expedited manner and in electronic form: **All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).**

Freedom Coalition of Doctors for Choice is a nonprofit and asks that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that "disclosure of the [requested] information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government[.]" The disclosure of the requested information will contribute to the public's understanding in at least three ways: (1) the disclosure of the requested information will provide the public with primary source documentation of the reactions v-safe participants experienced during regularly set intervals after receiving various doses of the COVID-19 vaccines originally approved under the government issued Emergency Use Authorization; (2) this data will shed light on the overall safety and efficacy of the COVID-19 vaccines for the over 10 million v-safe participants, a substantial sample size to synthesize important information regarding the vaccines' safety and efficacy; and (3) the disclosure of the information described above will shed light on whether CDC and other health agencies appropriately monitored and acted upon the information provided by v-safe participants. The information the Organization requests will not contribute to any commercial activities.

Furthermore, the Organization also requests CDC provide expedited processing for this request. The information requested concerns matters of urgent public concern. The Organization's request for expedited processing should be granted because it qualifies under the "compelling need" analysis, as defined by FOIA. FOIA provides for "expedited processing of requests for records" upon a showing of a "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(I). A requestor shows a "compelling need" when it is (1) "primarily engaged in disseminating information," and (2) there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II). This request demonstrates both requirements below:

The requester is primarily engaged in disseminating information

The Freedom Coalition of Doctors for Choice is a not-for-profit organization that exists for the sole purpose of obtaining and disseminating to the public the free-text fields in the CDC's v-safe database. It is made up of medical and public health professionals, scientists, and journalists. Many of these individuals individually share with the public their findings, research, and professional opinions about Covid-19 and related issues. The coalition itself takes no position on this data other than that it should be made available to the public and the scientific community as soon as possible. It pledges that all data obtained from this request will be made available on its website – drsforchoice.org – upon receipt.

There is an urgency to inform the public concerning actual or alleged Federal Government activity.

In determining whether there is an “urgency to inform,” and hence a “compelling need,” courts must consider at least three factors: (1) whether the request concerns a matter of current exigency to the American public; (2) whether the consequences of delaying a response would compromise a significant recognized interest; and (3) whether the request concerns Federal Government activity. *Al-Fayed v. CIA*, 254 F.3d 300, 310 (D.C. Cir. 2001). All three factors are present here and weigh in favor of granting expedited processing of the Organization's FOIA request.

CDC is the federal agency responsible for administering and monitoring the v-safe program. CDC's website describes v-safe as an internet-based program that allows participants to “tell CDC how you, or your dependent, feel after getting any dose of COVID-19 vaccine.”¹ One of the purposes of the program “is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions.”² A major source of information CDC could use to detect and evaluate clinically important adverse events and safety issues was the data obtained from v-safe users/registrants, generated from the free text questions and responses within the v-safe program – the same information the Organization seeks in this request.

The contents of the information sought by this request could be analyzed and synthesized in meaningful ways to enable the public to better understand the potential benefits and risks involved in taking COVID-19 vaccines – or as the CDC currently recommends to all people ages 5 years and older – the COVID-19 vaccine booster.³ Without this information, which the CDC currently possesses but has not disclosed, the public is missing critical primary source information regarding v-safe participants' experiences taking the COVID-19 vaccines and the recommended boosters. Preventing the public and the scientific community from immediately accessing,

¹ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html>.

² <https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf>.

³ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html>.

analyzing, and synthesizing this information compromises the public's significant recognized interest of informed consent.⁴

The information sought is more urgent than ever because the federal government has recently implemented policies and messaging campaigns in order to promote the public's consent and access to the COVID-19 vaccines and boosters. However, to derive the public's informed consent, the federal government has an obligation to balance its messaging with – at the very least – access to the information it possesses regarding the possible risks and harms from receiving these medical products.

For example, transparency is even more critical now that the Advisory Committee on Immunization Practices (ACIP) has voted to add the COVID-19 vaccines to the routine childhood immunization schedule.⁵ This new policy may very likely cause states to create policies that grant or restrict certain privileges, such as attending school, based upon a child's COVID-19 vaccination status. Without disclosure, parents who are confronted with COVID-19 vaccine mandates are forced to choose between allowing their children to receive a vaccine without all the information available to make an informed decision, or their child being prevented from receiving an education based upon their vaccination status. Therefore, no matter a parent's choice when confronted with a COVID-19 vaccine mandate, a delay in the disclosure of the information sought in this request would compromise the public's significant recognized interest of informed consent.

As another example, the Biden administration has recently launched a major messaging campaign to increase the public's interest in receiving COVID-19 boosters.⁶ With the Biden administration's "new push to encourage families to get the updated COVID-19 vaccine" which includes "vaccination events" at "Head Start provider locations" under HHS' "#VaxUpAmerica Family Vaccine Tour," it is critical that the public has the latest information regarding possible signals of adverse reactions from these vaccines.⁷ Any delay in the processing of the request would deny families the information they need to provide their informed consent to the external pressures and messaging resulting from the current administration's actions.

Therefore, as demonstrated above, the Organization has shown (1) it is primarily engaged in disseminating information, and (2) there is an urgency to inform the public concerning actual or alleged Federal Government activities. Thus, the Organization's request for expedited processing should be granted.

⁴ Notions of informed consent have been codified in jurisdictions across the United States. For example, in Texas, a "recovery may be obtained [when there is] negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent." Tex. Civ. Prac. & Rem. Code § 74.101. Similarly, in New York, "informed consent shall include as a minimum, the specific procedure or treatment or both, their reasons for it, the reasonably foreseeable risks and benefits involved, and the alternatives for care or treatment, if any" 10 NYCRR § 405.7 (b)(9).

⁵ <https://www.aha.org/news/headline/2022-10-21-acip-recommends-adding-covid-19-vaccine-information-immunization-schedules>.

⁶ <https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/25/fact-sheet-president-biden-to-announce-additional-efforts-to-help-americans-get-their-free-updated-covid-19-vaccine-this-fall/>.

⁷ *Id.*

CDC's records are subject to disclosure under FOIA and are not otherwise exempt from disclosure pursuant to FOIA's nine statutory exemptions. To the extent that a determination is made by CDC that any limited portions of the records described above will be withheld from disclosure for this request, the Organization requests that the CDC segregate and disclose any portions of the records that are not exempt. Please expressly identify any exempt responsive records (or portions thereof) and the applicable FOIA exemptions for any responsive materials withheld for this FOIA request.

Our organization also requests that the agency provide an estimated date of completion for this request. Please inform me in writing if there are any "unusual circumstances" that will cause delay in responding to this FOIA request or providing the records which are requested.

If you have any questions regarding this FOIA request, please feel free to contact me at Chris@cwiestlaw.com or 513-257-1895.

Thank you in advance for your assistance in processing this request.

Regards,

/s Christopher Wiest
Christopher Wiest

Attachment 2



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

January 12, 2023

SENT VIA EMAIL

Christopher Wiest
Attorney at Law, PLLC
25 Town Center Blvd. Suite 104
Crestview Hills, Kentucky 41017
Via email: chris@cwiestlaw.com

Dear Mr. Wiest:

This letter is in response to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of January 3, 2023. Your request assigned number is 23-00462-FOIA, seeking:

“All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded). Date range: 10/01/2020-12/31/2022.”

Please click on the following link to download a copy of the public v-safe data released by CDC. The data contains the registrant codes for all participants: <https://data.cdc.gov/Public-Health-Surveillance/v-safe/dqgu-gg5d>

Please be informed that the agency is withholding the v-safe free-text-fields data for the following reasons:

- There are 7.8 million free-text field entries collected in v-safe from registered users that contain personal identifiable information (PII).
- The agency lacks the resources to manually review the data collected from these registrants.

Alternatively, we are providing you with a copy of the “v-safe motivation survey” dataset. This dataset includes survey responses collected from v-safe participants from May 1, 2022, through June 31, 2022. After a careful review, some of the information has been withheld from release pursuant to FOIA Exemption 6.

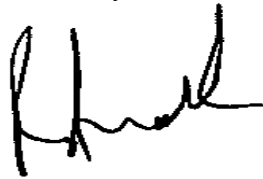
Please click on the following link or copy into a web browser to download a copy of your records (download access is open for 90 days).

<https://centersfordiseasecontrol.sharefile.com/d-s43a2254979c94ab6b5c52584509a351f>

Appeal Rights

If you are not satisfied with the response to this request, you may administratively appeal to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, via the online portal at <https://requests.publiclink.hhs.gov/App/Index.aspx>. Your appeal must be electronically transmitted by April 13, 2023.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. Andoh', with a stylized flourish at the end.

Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
Phone: (770) 488-6399
Fax: (404) 235-1852

#23-00462-FOIA

Attachment 4



Case No. 2023-00067-A-PHS

January 17, 2023

Christopher Wiest
25 Town Center Boulevard, STE 104
Crestview Hills, Kentucky 41017
Via email: chris@wiestlaw.com

Dear Mr. Wiest:

This letter acknowledges receipt of your Freedom of Information Act (FOIA) appeal, which was submitted on behalf of the Freedom Coalition of Doctors for Choice to the Department of Health and Human Services (HHS), FOI/Privacy Acts Division. We received your appeal on January 17, 2023. It challenges the Centers for Disease Control and Prevention (CDC) response to your initial request, 23-00462-FOIA. We assigned your appeal the tracking number above based on when it was received in this office. Please refer to this number on any future correspondence.

Pursuant to 5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(B)(iii) of the FOIA and 45 C.F.R. § 5.24(f) of the HHS FOIA regulations, your appeal falls under “unusual circumstances” in that our office will need to consult with another office or agency that has substantial interest in the determination of the appeal. The actual processing time will depend on the complexity of the issues presented in the appeal and consultation with other U.S. Department of Health and Human Services (HHS) components involved.

Each appeal is handled on a first-in, first-out basis in relation to the other open appeals in the processing queue. Currently, there are approximately 450 open appeals in the processing queue. For more information about how your appeal will be processed please refer to the HHS FOIA regulations (<https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations>).

As a final note, if you are not already submitting your appeals through our Public Access Link (PAL), we recommend all future appeals be submitted through PAL - <https://requests.publiclink.hhs.gov/>. Submitting appeals through PAL automatically logs your appeal into our tracking system and provides you with a tracking number. Your PAL account will allow you to track the progress of your appeal, receive your response directly through the portal, and securely submit privacy-sensitive or business-sensitive documents.

If you have any questions, please email us at foiarequest@psc.hhs.gov.

Sincerely yours,

Alesia Y. Williams

Alesia Y. Williams
Director, FOIA Appeals and Litigations
FOI/Privacy Acts Division

Attachment 5

V-safe active surveillance for COVID-19 vaccine safety

Protocol summary

V-safe is an active surveillance program to monitor the safety of COVID-19 vaccines during the period when the vaccines are authorized for use under Food and Drug Administration (FDA) Emergency Use Authorization (EUA) and possibly early after vaccine licensure. V-safe is a new smartphone-based system that uses text messaging to initiate web-based survey monitoring in the form of periodic health check-ins to assess for potential adverse events following vaccination. CDC will use the follow-up capability of the existing Vaccine Adverse Event Reporting System (VAERS) call center to conduct active telephone follow-up on recipients reporting a significant health impact during v-safe health check-ins. The purpose of v-safe surveillance is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions.

Background and significance

Coronavirus disease 2019 (COVID-19) is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Following the emergence of COVID-19 in China in late 2019, the first confirmed U.S. cases were detected in January 2020. With rapid human-to-human transmission occurring, the United States declared a public health emergency in February 2020, followed by a national emergency in March 2020 (1). As of November 18, 2020, there have been 11,300,635 cases of COVID-19 disease in the United States and 247,834 deaths (2). A key U.S. pandemic response initiative is Operation Warp Speed, a public-private partnership established in May 2020, with a goal to develop and deliver safe and effective COVID-19 vaccine(s) to the U.S. population by early 2021 (3).

Post-authorization/post-approval vaccine safety monitoring is a federal government responsibility, with the Centers for Disease Control and Prevention (CDC) and the FDA sharing most of the responsibility along with other federal agencies involved in healthcare delivery (e.g., Veterans Affairs, Department of Defense, Indian Health Service). Initial safety assessment

begins in early vaccine development and expands during phased clinical trials in humans. Clinical trials are effective at identifying and characterizing common adverse events, such as local and systemic reactions. However, even large clinical trials, like the COVID-19 vaccine clinical trials that are enrolling tens of thousands of volunteers, might not be large enough to detect rare adverse events (for example, those occurring at rates of <1 per 100,000 people vaccinated). Furthermore, for some clinical trials of COVID-19 vaccines, the follow-up period to monitor for possible adverse events with delayed onset may not be completed for all subjects prior to issuance of an EUA or licensure. Additionally, exclusion criteria for clinical trials may limit generalizability of safety and efficacy findings to special populations, such as those with certain chronic illnesses or pregnant women (4). For these reasons, robust post-authorization/approval safety monitoring of COVID-19 vaccines is a public health priority.

To meet the safety data needs for COVID-19 vaccine pharmacovigilance during the post-authorization/approval period, CDC will implement v-safe, a smartphone-based system that uses text messaging to initiate web-based surveys to monitor for adverse events following vaccination. The surveillance process triggers active telephone follow-up on vaccinated individuals reporting a significant health impact during v-safe health check-ins.

Goals and objectives

Goals

- Characterize the safety profile of COVID-19 vaccines.
- Rapidly monitor and identify potential safety problems associated with COVID-19 vaccines that would impact policy or regulatory decisions.

Objectives

- Characterize the local and systemic reactogenicity of COVID-19 vaccines during the first week post-vaccination (days 0-7).
- Identify and characterize clinically important adverse events following COVID-19 vaccination during a 6-week post-vaccination follow-up period.

- Monitor the long(er)-term (3, 6, and 12 months post-vaccination) safety of COVID-19 vaccines.

Methods

Surveillance population

All people in the United States who receive a COVID-19 vaccination will be eligible to enroll in v-safe for the duration of the v-safe program. Surveys will be available in English, Spanish, Simplified Chinese, Vietnamese, and Korean languages.

Enrollment criteria:

- Participants must have received a COVID-19 vaccination.
- Participants must possess a smartphone with a valid US telephone number. More than one individual may use the same smartphone/telephone number (i.e., shared smartphone).

Enrollment

The v-safe program will commence when COVID-19 vaccines are authorized or approved for use and become available to the U.S. population. Vaccination may occur at a mass vaccination clinic, an occupational health clinic, a public health clinic, a healthcare provider's office, a pharmacy, or other setting. At the time of vaccination, the healthcare provider will briefly describe the v-safe program using a prescribed script (Attachment 1). In addition, the healthcare provider will provide the vaccinated patient with an information sheet that includes a brief description of the program, a URL and a scannable QR code, and enrollment instructions.

Vaccinated individuals can enroll in v-safe immediately following vaccination. If they do not enroll immediately, they can decide to participate in v-safe at any time up to 42 days following the first vaccination. For vaccine recipients whose vaccination information is captured in CDC's Vaccine Administration Management System (VAMS), VAMS will send recipients a reminder text message about v-safe 24 hours after vaccination (5). Participation in v-safe is voluntary and

people can opt out at any time by texting “STOP” when v-safe sends a reminder text message; people can also start v-safe again by texting “UNSTOP.”

Once a vaccinated individual decides to enroll in v-safe, the individual will either scan his/her mobile phone camera over the QR code on the information sheet or type in the v-safe URL to access the v-safe registration website.

Registration information includes:

- First name
- Last name
- Mobile phone number
- Date of birth
- Sex
- Zip code

The registration system will ask the participant to verify their phone number by sending a text message with a verification code. The participant will enter the texted code to verify their identity. After that, the participant will be asked to record information on their first COVID-19 vaccination, including the vaccine manufacturer and the vaccination date. If the v-safe participant does not know this information, they are encouraged to refer to the vaccination record card they received or to contact their healthcare provider.

Once a participant has registered and provided information on their COVID-19 vaccination, they will be prompted to take an initial v-safe health check-in survey. The survey will be dependent on the vaccination date and dose number (if applicable) entered during registration. Subsequently, text messages will be sent to their smartphone with a link to a web-based survey at 2:00 pm (local time based on zip code entered at registration) on the schedule listed below.

Electronic health check-in schedule

The schedule for electronic health check-ins is as follows:

1. Day 0 (day of vaccination)
2. Daily on days 1-7 (the 1st week post-vaccination)
3. Weekly starting day 14 (2nd week post-vaccination) to up to day 42 (6th week post-vaccination) if no 2nd dose of COVID-19 vaccine is received
 - a. If participant receive a 2nd COVID-19 vaccine dose during the post-vaccination follow-up period, the process will reset to day 0 for the 2nd dose and continue through steps 1-3 above based on time since the 2nd dose.
4. At 3, 6, and 12 months post-vaccination following 2nd dose vaccination or following first dose if no 2nd dose is received

Daily surveys expire at midnight on the day of the survey and weekly surveys expire at midnight on the last day of the week before the next weekly survey period. The day 42 survey will expire on day 48 at midnight. Monthly surveys will be available for 6 full days following receipt of the survey, expiring at midnight. A participant can enroll in v-safe up to 42 days during the post-vaccination follow-up period after the first dose, but cannot go back and complete surveys that have expired (i.e., it will be prospective from the time of enrollment). In addition, a participant cannot revise their survey once it has been submitted. After submission, the participant is told that depending on his/her answers, someone from CDC might call to follow up.

Active telephone follow-up

If, during any v-safe health check-in, a participant reports a significant health impact event, defined as per the survey: a) missed work, and/or b) unable to do normal daily activities, and/or c) got care from a doctor or other healthcare professional, VAERS call center staff will be informed and active telephone follow-up will be initiated to check on the patient and take a VAERS report if appropriate. [VAERS](#) is an existing national spontaneous reporting system that is co-managed by FDA and CDC. It serves as an early warning system for adverse events following vaccination (6).

VAERS call center staff will be notified of participants who have reported a significant health impact event via a data set that will be created from the v-safe survey system. The data set will include the following variables:

- Unique v-safe id
- First name
- Last name
- Phone number
- Sex
- Zip code
- Flagged health impact question
- Flagged health impact response(s) survey number (dose/survey [i.e., Dose2D0])

Using this information, the VAERS call center staff will call participants identified in the data set and complete a VAERS report (located at <https://vaers.hhs.gov>) by phone if appropriate.

Data collection, quality, and management

V-safe data will be collected, managed, and housed on a secure server by Oracle. Through Health and Human Services (HHS), Oracle has donated IT services to any agency conducting COVID-19 related activities. Oracle is providing IT support for v-safe. All data will be stored, processed, and transmitted in accordance with the Federal Information Security Modernization Act (FISMA) and based on NIST standards. Data will be housed in *Oracle Cloud Infrastructure (OCI) U.S. Government Cloud tenancy*; the OCI U.S. government tenancy is Federal Risk and Authorization Management Program (FEDRAMP) approved (7).

Per Oracle's internal policies, Oracle staff will not be able to view any individualized survey data (including variables with personally identifiable information [PII]) but, rather, will have access to aggregate deidentified data for reporting. CDC will have "read" access to the individualized survey data, including PII, provided by Oracle. On a continuous basis (either daily or weekly), these survey data will be accessible to CDC through downloads from the CDC IT contractor's secure server. The v-safe system employs strict security measures appropriate for the level of sensitivity of the data. Data received by CDC will be stored on an internal secure CDC/ISO server and access will be limited to authorized personnel.

Oracle will create a data set for the VAERS call center that includes those participants who reported having a health impact event. CDC-badged contractors will access these data in order to provide call center representatives with information needed to follow up with participants (see “Active telephone follow-up” above). The VAERS call center staff is employed specifically for v-safe follow-up and is associated with the overall VAERS contractor.

VAERS reports will be obtained during active telephone follow-up with v-safe participants and will be processed, handled, stored, and accessed in accordance with existing approved VAERS procedures and policies.

Data from all components of v-safe, as well as VAERS reports obtained through the call center, may be combined into a master data set behind the CDC firewall using unique identification numbers assigned at registration.

Preapproved CDC investigators and data managers, including CDC contractors, will be the only individuals with access to the full data (v-safe, linked VAERS reports). All electronic documents, data sets, and files relevant to the project will be stored on network folders with restricted access on CDC computers. The v-safe team at CDC will be primarily responsible for data management activities, including data extraction, documentation, and archival of a final data set for data sharing purposes. The archive will include the protocol, statistical programs, human subjects review documents, statistical output, analytical data sets, and manuscripts. It will clearly identify the permanent storage location for these files.

A final data set at the end of the v-safe program with deidentified aggregate data will be made available for external data requests or through Freedom of Information Act (FOIA) requests.

Analysis plan

Descriptive analyses will be conducted using the data collected through surveys on a weekly basis during the surveillance period. Participation rates over time will also be calculated.

For v-safe participants who have a VAERS report submitted through the VAERS call center, additional analyses will be conducted. Rates of serious events as well as adverse events of special interest (AESI) following COVID-19 vaccination will be generated using VAERS reports solicited via v-safe to define the numerator and v-safe participants as the denominator (Attachment 2). VAERS reports that are considered serious or AESI will be reviewed by medical staff at CDC. Case definitions (Brighton Collaboration or other standard definitions as appropriate) will be applied to the AESIs. Reporting rates for each AESI will be calculated and compared to established background rates. If at any time rates observed in v-safe exceed what is expected from background rates, further investigation will occur within other vaccine safety monitoring systems, including VAERS and Vaccine Safety Datalink (7).

VAERS monitoring for all COVID-19 reports will include VAERS reports solicited from v-safe participants. Reports obtained from v-safe participants will be coded so that they can be distinguished from other VAERS reports and analyzed separately from other VAERS reports if needed.

Human subjects considerations and confidentiality

This protocol will require human subjects determination at CDC since CDC is the lead site and surveillance data will include collection of PII. No PII will be included in any v-safe analyses, manuscripts, or data sets shared through external data requests. Participation is completely voluntary and individuals self-enroll. Participants can opt out of v-safe at any time and their data will be used for the time they were considered an active participant. As an analysis of data collected for non-research purposes, this activity presents minimal risk to subjects, and use of patient data for this purpose will not adversely affect subjects' rights or welfare.

Duration

The anticipated duration of the v-safe program is approximately 6-8 months of active enrollment. The decision to discontinue v-safe or to modify v-safe procedures to scale back active telephone follow-up will be made in consultation with the CDC COVID-19 Vaccine Task Force leadership and FDA.

Limitations and challenges

Limitations and challenges for v-safe surveillance include:

- Enrollment and registration will initially be a manual process and will be dependent on healthcare providers sharing information about the system with vaccine recipients. Enrollment might be limited. While VAMS will help promote v-safe enrollment through automated text message reminders, not all jurisdictions will use VAMS, and VAMS text messaging capabilities may not be rolled out until several weeks/months after vaccine becomes available.
- Accurate capture of vaccine manufacturer information will depend on accurate self-report, at least initially. Vaccine recipients are expected to receive vaccination record cards specifying the vaccine they received, which might help to improve accuracy of these data.
- Vaccinated people who choose to participate in v-safe might be different from those who decline; therefore, rates of side effects and adverse events generated from v-safe might not be generalizable to the full population of vaccine recipients.
- V-safe allows people to enter late in the post-vaccination monitoring period. The group of individuals who enroll in v-safe late might be heterogeneous—those who simply neglected to enroll early, those who chose to enroll only after experiencing a clinically important adverse event, and others. Data collected from these individuals may need to be analyzed separately from data from those who enrolled early.
- The information provided by v-safe participants at 3, 6, and 12 months after vaccination might be impacted by recall bias.

- Participants will likely be lost to follow-up at later time points, reducing participant numbers and likely creating biases in v-safe analyses of safety out to 12 months.
- Because v-safe relies on vaccine recipients reporting their own experiences after vaccination, v-safe is not conducive to capturing the adverse event of death following vaccination.

Dissemination


Data from v-safe will be important in the beginning phases of the COVID-19 vaccination program. Regular updates will be provided to advisory committees and data review groups. It is anticipated that v-safe data will be shared with the scientific community and with the public through manuscripts and public reports.

References

1. *The American Journal of Managed Care*. A Timeline of COVID-19 Developments in 2020. Available at <https://www.ajmc.com/view/a-timeline-of-covid19-developments-in-2020>.
2. CDC. CDC COVID Data Tracker. Available at https://covid.cdc.gov/covid-data-tracker/#cases_casesinlast7days.
3. Slaoui M, Hepburn M. Developing Safe and Effective Covid Vaccines—Operation Warp Speed’s Strategy and Approach. *N Engl J Med* 2020; 383:1701–1703.

4. Su JR, Duffy J, Shimabukuro TT (2019). Chapter 1: Vaccine Safety. In Poland GA (Ed.) and Whitaker JA (Assoc. Ed.), *Vaccinations*. St. Louis, MO: Elsevier.
5. https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf
6. Shimabukuro TT, Nguyen M, Martin D, DeStefano F. Safety monitoring in the Vaccine Adverse Event Reporting System (VAERS). *Vaccine*. 2015; 33(36): 4398–4405.
7. <https://www.gsa.gov/technology/government-it-initiatives/fedramp>)?
8. McNeil MM, Gee J, Weintraub E, et al. The Vaccine Safety Datalink: successes and challenges monitoring vaccine safety. *Vaccine*. 2014; 32(42):5390–8.

Attachment 1: V-safe survey script
Registration and my account:
Landing page:



**Get vaccinated.
Get your smartphone.
Get started with v-safe.**

V-safe is a smartphone-based tool that checks in on you after your COVID-19 vaccination. Your participation helps keep COVID-19 vaccines safe — for you and for everyone.

If you got vaccinated in the last 6 weeks, you can participate in v-safe!

It takes just a few minutes to register and get started. All you need is your smartphone and information about the COVID-19 vaccine you received. This information can be found on your vaccination record card. If you cannot find your card, please contact your healthcare provider.

1

Register for v-safe
Enter basic information about yourself and follow the prompts to set up your account.

2



Enter your vaccine information
Tell us which COVID-19 vaccine you received and when you got it.

3


Start your health check-ins!
You will receive text reminders when it is time to complete your health check-ins.

Get Started

Your information in v-safe is protected by administrative, technical, and physical measures that safeguard the confidentiality, integrity, and privacy of personal information. To the extent v-safe uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the level of sensitivity of the data. These measures comply, where applicable, with the following federal laws: the Privacy Act of 1974; standards enacted consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act; and the Freedom of Information Act. [Learn more about v-safe.](#)



Registration page



Registration

First Name

Last Name

Mobile Phone

☐ Yes, I agree to receive notifications from this system (messaging and data rates may apply).

Date of Birth *

Month Day Year

Sex


ZIP Code

Register

[Already Registered? >](#)

Your information in v-safe is protected by administrative,

Registration completed:



Registration

First Name
Olivia

Last Name
Jackson

Mobile Phone
7035551234

☒ Yes, I agree to receive notifications from this system (messaging and data rates may apply).

Date of Birth *

June 1 1980

Sex
Female


ZIP Code
20020

Register

[Already Registered? >](#)

Your information in v-safe is protected by administrative,


Verification:



Hello, Olivia

We sent a verification code to your phone number ending in **1234**.

Please enter the six-digit code below to complete your registration.





306119


Send code again


Verify

Account:



Hello, Olivia


Welcome to v-safe!
Please enter your COVID-19 vaccine information to start your health check-ins.
[Enter Vaccine Information](#)




[View My Profile](#)


REGISTRANT CODE
CDX-13331-46622


DATE OF BIRTH
June 1st 1980


MOBILE NUMBER
703-555-1234

Your information in v-safe is protected by administrative, technical, and physical measures that safeguard the confidentiality, integrity, and privacy of personal information. To the extent v-safe uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the level of sensitivity of the data. These measures comply, where applicable, with the following federal laws: the Privacy Act of 1974; standards enacted consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act; and the Freedom of Information Act. [Learn more about v-safe.](#)

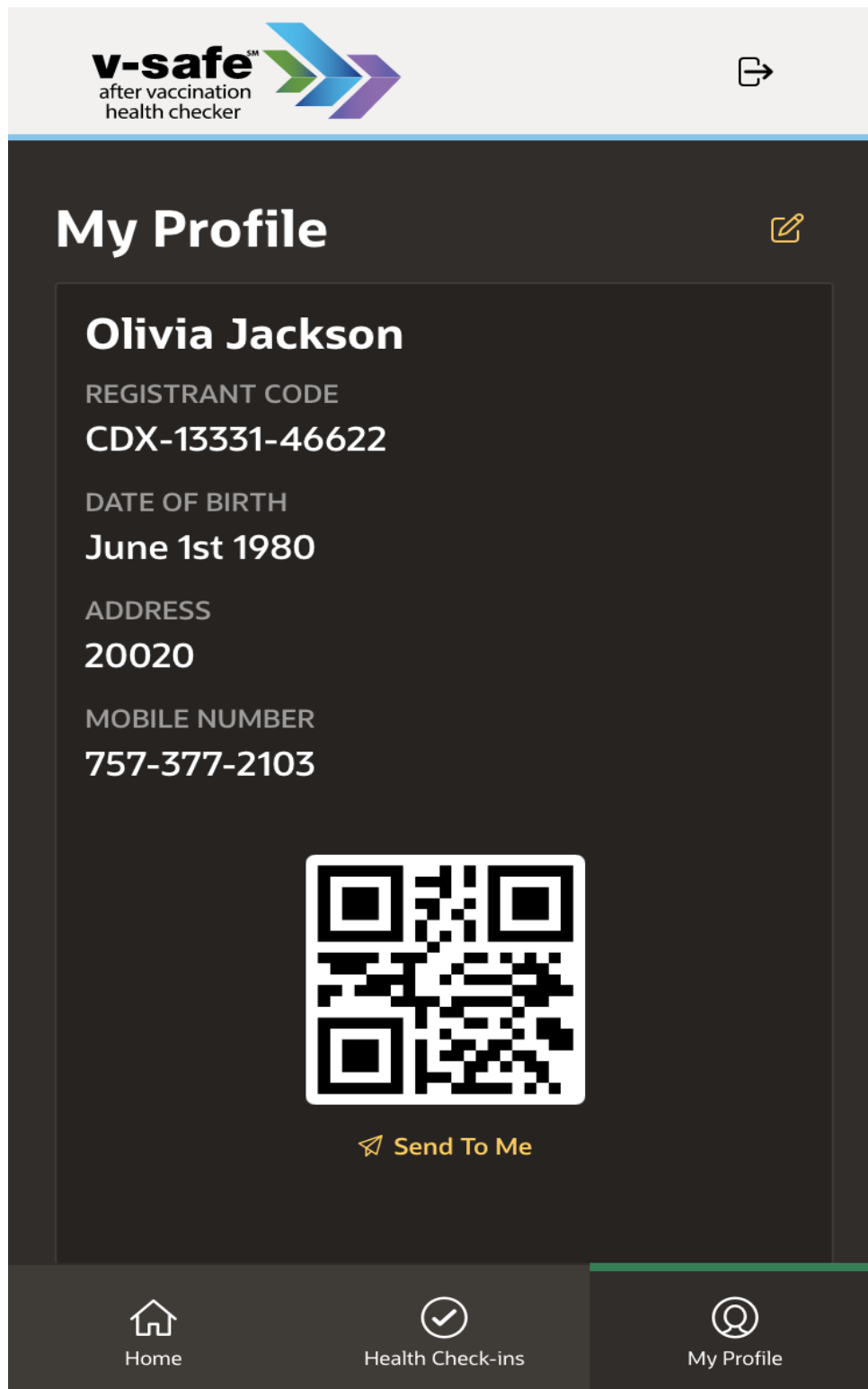



Home




Health Check-ins


My Profile

My profile:



Enter vaccine:



Enter your vaccine information

Tell us about the **first COVID-19 vaccine** you received and when you got it. You can find this information on your COVID-19 vaccination record card. If you cannot find your card, please contact your healthcare provider.

Please select which company made your COVID-19 vaccine *

AstraZeneca

Johnson and Johnson

Moderna

Novovax

Pfizer-BioNTech

Please enter the date you got your COVID-19 vaccine *

December



15

2020

Next >

Cancel

Your information in v-safe is protected by administrative, technical, and physical measures that safeguard the confidentiality, integrity, and privacy of personal information. To the extent v-safe uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the level of sensitivity of the data. These measures comply, where applicable, with the following federal laws: the Privacy Act of 1974; standards enacted consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act; and the Freedom of Information Act. [Learn more about v-safe.](#)

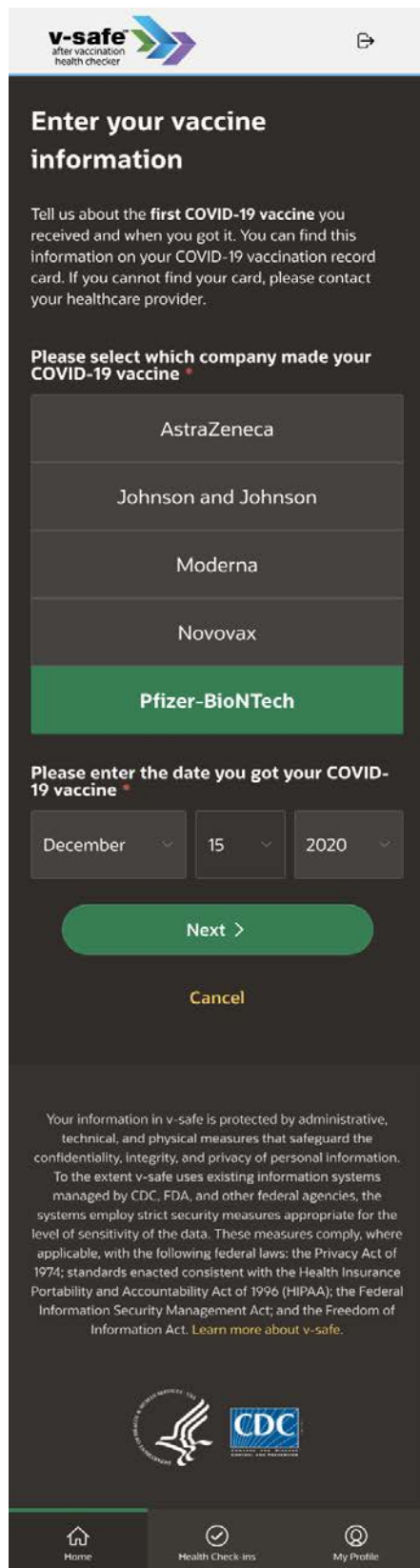


Home

Health Check-ins

My Profile

Enter vaccine- completed:



The image shows a mobile app interface for 'v-safe after vaccination health checker'. The screen is titled 'Enter your vaccine information'. Below the title, there is a paragraph of text: 'Tell us about the first COVID-19 vaccine you received and when you got it. You can find this information on your COVID-19 vaccination record card. If you cannot find your card, please contact your healthcare provider.' Below this text, there is a prompt: 'Please select which company made your COVID-19 vaccine *'. There are five buttons for selection: 'AstraZeneca', 'Johnson and Johnson', 'Moderna', 'Novovax', and 'Pfizer-BioNTech'. The 'Pfizer-BioNTech' button is highlighted in green. Below the buttons, there is another prompt: 'Please enter the date you got your COVID-19 vaccine *'. There are three dropdown menus for the date: 'December', '15', and '2020'. Below the date inputs, there is a green 'Next >' button and a yellow 'Cancel' button. At the bottom of the screen, there is a footer with a paragraph of text about data protection and privacy, followed by logos for the Department of Health and Human Services and the CDC. At the very bottom, there is a navigation bar with three icons: 'Home', 'Health Check-ins', and 'My Profile'.

v-safe
after vaccination
health checker

Enter your vaccine information

Tell us about the **first COVID-19 vaccine** you received and when you got it. You can find this information on your COVID-19 vaccination record card. If you cannot find your card, please contact your healthcare provider.

Please select which company made your COVID-19 vaccine *

AstraZeneca

Johnson and Johnson

Moderna

Novovax

Pfizer-BioNTech

Please enter the date you got your COVID-19 vaccine *

December 15 2020

Next >



Cancel

Your information in v-safe is protected by administrative, technical, and physical measures that safeguard the confidentiality, integrity, and privacy of personal information. To the extent v-safe uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the level of sensitivity of the data. These measures comply, where applicable, with the following federal laws: the Privacy Act of 1974; standards enacted consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act; and the Freedom of Information Act. [Learn more about v-safe.](#)

DEPARTMENT OF HEALTH & HUMAN SERVICES
CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Home Health Check-ins My Profile

Confirm vaccine:




Confirm your vaccine information



Please confirm the following information is correct.


Manufacturer
Pfizer-BioNTech
Dose
1
Vaccination Date
Tuesday, December 15, 2020


Submit


 **Go Back**

Your information in v-safe is protected by administrative, technical, and physical measures that safeguard the confidentiality, integrity, and privacy of personal information. To the extent v-safe uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the level of sensitivity of the data. These measures comply, where applicable, with the following federal laws: the Privacy Act of 1974; standards enacted consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act; and the Freedom of Information Act. [Learn more about v-safe.](#)



 Home

 Health Check-ins

 My Profile

V-safe Dose 1 surveys through Day 42

DAY 0- Dose 1:

Text message invitation::

Hi <NAME>. It's time for your first v-safe check-in. (*link to personalized v-safe survey*)

Survey:

Hi <name>.

Let's start today's health check-in.

How are you feeling today? 😊

☐ Good ☐ Fair ☐ Poor

Fever check

Since your vaccination, have you had a fever or felt feverish?

☐ Yes ☐ No

(If Yes) Do you know your highest temperature reading from today?

- ☐ Yes- in degrees Fahrenheit
- ☐ Yes- in degrees Celsius
- ☐ No- I don't remember the reading
- ☐ No- I didn't take my temperature

Enter your highest temperature reading from today (degrees Fahrenheit): _____

Enter your highest temperature reading from today (degrees Celsius): _____

Symptom check

Symptoms can be classified as:

Mild = you notice symptoms, but they aren't a problem

Moderate = symptoms that limit of your normal daily activities

Severe = symptoms make normal daily activities difficult or impossible

Have you had any of these symptoms at or near the injection site?

select all that apply: ☐ Pain ☐ Redness ☐ Swelling ☐ Itching ☐ None

How would you rate your symptoms:

- | | | | |
|-----------------------|-------------------------------|-----------------------------------|---------------------------------|
| (If checked Pain) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |
| (If checked Redness) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |
| (If checked Swelling) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |
| (If checked Itching) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |

Have you experienced any of these symptoms today?

Select all that apply.

☐ Chills

- ☐ Headache
- ☐ Joint pain
- ☐ Muscle or body aches
- ☐ Fatigue or tiredness
- ☐ Nausea
- ☐ Vomiting
- ☐ Diarrhea
- ☐ Abdominal pain
- ☐ Rash, not including the immediate area around the injection site
- ☐ None

Any other symptoms or health conditions you want to report _____

Symptoms can be classified as:

Mild = you notice symptoms, but they aren't a problem

Moderate = symptoms that limit of your normal daily activities

Severe = symptoms make normal daily activities difficult or impossible

- (If checked Chills) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Headache) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Joint pain) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Muscle or body aches) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Fatigue or tiredness) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Nausea) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Vomiting) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Diarrhea) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Abdominal pain) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Rash, not including the immediate area around the injection site) ☐ Mild
☐ Moderate ☐ Severe

Health impact

Did any of the symptoms or health conditions you reported TODAY cause you to (select all that apply):

- ☐ Be unable to work?
- ☐ Be unable to do your normal daily activities?
- ☐ Get care from a doctor or other healthcare professional?
- ☐ None of the above

(If "Get care..." checked) What type of healthcare visit did you have? (check all that apply)

- ☐ Telehealth, virtual health, or email health consultation
- ☐ Outpatient clinic or urgent care clinic visit

- ☐ Emergency room or emergency department visit
- ☐ Hospitalization
- ☐ Other, describe:

Were you pregnant at the time of your COVID-19 vaccination?

(This is only asked for the only initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)

☐ ☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

Thanks for completing today's check-in.

Depending on your answers, CDC may call you to get more information about your symptoms.

If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

We'll be in touch tomorrow.

Days 1-7 post vaccination

Text message & reminder:

Invitation text: Hi, <name>. It's time for your daily v-safe check-in. (*link to personalized survey*)

Reminder text (for Day 7 survey only): Hi <name>, Please remember to do your daily v-safe check-in. (*link to personalized survey*)

Online survey from link in text message above

Hi <name>.

Let's start today's health check-in.

How are you feeling today? 😊

☐ Good ☐ Fair ☐ Poor

Fever check

Have you had a fever or felt feverish TODAY?

☐ No ☐ Yes

(If Yes) Do you know your highest temperature reading from today?

- ☐ Yes- in degrees Fahrenheit
- ☐ Yes- in degrees Celsius
- ☐ No- I don't remember the reading
- ☐ No- I didn't take my temperature

Enter your highest temperature reading from today (degrees Fahrenheit)

Enter your highest temperature reading from today (degrees Celsius)

Symptom check

Symptoms can be classified as:

Mild = you notice symptoms, but they aren't a problem

Moderate = symptoms that limit your normal daily activities

Severe = symptoms make normal daily activities difficult or impossible

Have you had any of these symptoms at or near the injection site today?

Check all that apply: ☐ Pain ☐ Redness ☐ Swelling ☐ Itching ☐ None

(If checked Pain) ☐ Mild ☐ Moderate ☐ Severe

(If checked Redness) ☐ Mild ☐ Moderate ☐ Severe

(If checked Swelling) ☐ Mild ☐ Moderate ☐ Severe

(If checked Itching) ☐ Mild ☐ Moderate ☐ Severe

Have you experienced any of these symptoms today?

Select all that apply:

☐ Chills

☐ Headache

- ☐ Joint pain
- ☐ Muscle or body aches
- ☐ Fatigue or tiredness
- ☐ Nausea
- ☐ Vomiting
- ☐ Diarrhea
- ☐ Abdominal pain
- ☐ Rash, not including the immediate area around the injection site
- ☐ None

Any other symptoms or health conditions you want to report_____

Symptoms:

Symptoms can be classified as:

Mild = you notice symptoms, but they aren't a problem

Moderate = symptoms that limite your normal daily activities

Severe = symptoms make normal daily activities difficult or impossible

(If checked Chills) ☐ Mild ☐ Moderate ☐ Severe

(If checked Headache) ☐ Mild ☐ Moderate ☐ Severe

(If checked Joint pain) ☐ Mild ☐ Moderate ☐ Severe

(If checked Muscle or body aches) ☐ Mild ☐ Moderate ☐ Severe

(If checked Fatigue or tiredness) ☐ Mild ☐ Moderate ☐ Severe

(If checked Nausea) ☐ Mild ☐ Moderate ☐ Severe

(If checked Vomiting) ☐ Mild ☐ Moderate ☐ Severe

(If checked Diarrhea) ☐ Mild ☐ Moderate ☐ Severe

(If checked Abdominal pain) ☐ Mild ☐ Moderate ☐ Severe

(If checked Rash, not including the immediate area around the injection site_ ☐ Mild
☐ Moderate ☐ Severe

Health impact

Did any of the symptoms or health conditions you reported today cause you to (Select all that apply):

- ☐ Be unable to work?
- ☐ Be unable to do your normal daily activities?
- ☐ Get care from a doctor or other healthcare professional?
- ☐ None of the above

(If "Get care..." checked) What type of healthcare visit did you have? (check all that apply)

- ☐ Telehealth, virtual health, or email health consultation
- ☐ Outpatient clinic or urgent care clinic visit
- ☐ Emergency room or emergency department visit
- ☐ Hospitalization

☐ Other, describe:

Were you pregnant at the time of your COVID-19 vaccination?

(This is only asked for the only initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)

☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

Thanks for completing today's check-in.

Depending on your answers, CDC may call you to get more information about your symptoms.

If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

We'll be in touch for your next check-in.

14 days (2 weeks) survey following COVID-19 vaccination:

Text message

Invitation: Hi <name>. It's time for your weekly v-safe check-in. (*link to personalized survey*)

Reminder(text sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey*)

Online survey from link in text message above

Hi <name>.

Let's start today's health check-in.

How are you feeling today? 😊

☐ Good ☐ Fair ☐ Poor

Since your last check-in, have you experienced any new symptoms or worsening health conditions?

☐ Yes ☐ No

(if Yes) Please describe:

(if Yes) Did any of these symptoms or health conditions cause you to (check all that apply):

☐ Be unable to work?
☐ Be unable to do your normal daily activities?
☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) What type of healthcare visit did you have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation
☐ Outpatient clinic or urgent care clinic visit
☐ Emergency room or emergency department visit
☐ Hospitalization

☐ Other, describe:

Since your last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

☐ Yes ☐ No

(if Yes) When were you diagnosed? _____(mm/dd/yyyy)_

Were you pregnant at the time of your COVID-19 vaccination?

(This is asked only for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)

☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

Thanks for completing today's check-in.

Depending on your answers, CDC may call you to get more information about your symptoms. If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).

Alternate onscreen completion message FOR PFIZER and NOVOVAX RECIPIENTS:

Thanks for completing today's check-in.

Depending on your answers, CDC may call you to get more information about your symptoms.

You'll need to get your 2nd COVID-19 vaccine next week. Please remember to make an appointment if you have not done so already!

After you receive your 2nd COVID-19 vaccination, please sign into your v-safe account and update your vaccination information.

If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

21 days (3 weeks) following COVID-19 vaccination- DOSE

1:

Text message

Invitation: Hi <name>. It's time for your weekly v-safe check-in. (*link to personalized survey*)

Reminder (text sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey*)

Online survey from link in text message above

For Pfizer/Novovax recipients:

Hi <name>.

Let's start today's health check-in.

Did you get your 2nd COVID-19 vaccination?

☐ Yes ☐ No

(If YES) Thank you.

(*Survey will end and will be directed to enter Dose 2 information:.*)

Thank you for letting us know that you received your 2nd COVID-19 vaccine.

Please click the View My Account button below to view your account and register your 2nd COVID-19 vaccine.

For Moderna/AZ/Johnson & Johnson recipients & Pfizer/Novovax who did not get dose 2:

How are you feeling today? 😊

☐ Good ☐ Fair ☐ Poor

Since your last check in, have you experienced any new or worsening symptoms or health conditions?

☐ Yes ☐ No

(If Yes) Please describe the symptoms or health conditions.

(if Yes) Did any of these symptoms or health conditions cause you to (check all that apply):

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) What type of healthcare visit did you have? (check all that apply)

- ☐ Telehealth, virtual health, or email health consultation
 - ☐ Outpatient clinic or urgent care clinic visit
 - ☐ Emergency room or emergency department visit
 - ☐ Hospitalization
 - ☐ Other, describe:
-

Since your last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

☐ Yes ☐ No

(If Yes) When were you diagnosed? _____ (mm/dd/yyyy)

Were you pregnant at the time of your COVID-19 vaccination?

(This is asked only for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)

☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

For Moderna/AZ/:

Thanks for completing today's check-in.

Depending on your answers, someone from CDC may call you to check on you.

You'll need to get your 2nd COVID-19 vaccine next week. Please remember to make an appointment if you have not done so already!

After you receive your 2nd COVID-19 vaccination, please sign into your v-safe account and update your vaccination information.

If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

We'll be in touch next week.

For Pfizer/Novovax recipients who did not receive dose 2:

Thanks for completing today's check-in.

Depending on your answers, CDC may call you to get more information about your symptoms.

It is time to get your 2nd COVID-19 vaccine. Please remember to make an appointment if you have not done so already!

After you receive your 2nd COVID-19 vaccination, please sign into your v-safe account and update your vaccination information.

If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

28 days (4 weeks) following COVID-19 vaccination:

Text message

Invitation: Hi <name>. It's time for your weekly v-safe check-in. (*link to personalized survey*)

Reminder (text sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey*)

Online survey from link in text message above

For all Moderna, AZ and those Pfizer/Novovax who did not previously report Dose 2:

Hi <name>.

Did you get your 2nd COVID-19 vaccination?

☐ Yes ☐ No

(If YES) Thank you.

Survey will end and will be directed to enter Dose 2 information.

Thank you for letting us know that you received your 2nd COVID-19 vaccine.

Please click the View My Account button below to view your account and register your 2nd COVID-19 vaccine.

For Johnson & Johnson and all 2-dose vaccine recipients who report 'No' above

Hi <name>.

Let's start today's health check-in.

How are you feeling today? 😊

☐ Good ☐ Fair ☐ Poor

Since your last check-in, have you experienced any new or worsening symptoms or health conditions?

☐ Yes ☐ No

(If Yes) Please describe the symptoms or health conditions:

(if Yes) Did any of these symptoms or health conditions cause you to (check all that apply):

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

- ☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?
- ☐ None of the above

(If Yes to got care [above]) What type of healthcare visit did you have? (check all that apply)

- ☐ Telehealth, virtual health, or email health consultation
- ☐ Outpatient clinic or urgent care clinic visit
- ☐ Emergency room or emergency department visit
- ☐ Hospitalization
- ☐ Other, describe:
-

Since your last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

- ☐ Yes ☐ No

(if Yes) When were you diagnosed? _____(mm/dd/yyyy)_

Were you pregnant at the time of your COVID-19 vaccination?

(This is asked only for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)

- ☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

For Johnson & Johnson recipients:

Thanks for completing today's check-in.

Depending on your answers, CDC may call you to get more information about your symptoms.

If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

We'll be in touch next week.

For Pfizer/Novovax/Moderna/AZ recipients who did not receive dose 2:

Thanks for completing today's check-in.

Depending on your answers, CDC may call you to get more information about your symptoms.

It is time to get your 2nd COVID-19 vaccine. Please remember to make an appointment if you have not done so already!

After you receive your 2nd COVID-19 vaccination, please sign into your v-safe account and update your vaccination information.

If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

35 days (5 weeks) following COVID-19 vaccination:

Text message

Invitation: Hi <name>. It's time for your weekly v-safe check-in. (*link to personalized survey*)

Reminder (text sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey*)

Online survey from link in text message above

For all Moderna, AZ/ Pfizer/Novovax who did not previously report receipt of Dose 2:

Hi <name>.

Did you get your 2nd COVID-19 vaccination?

☐ Yes ☐ No

(If YES) Thank you.

Survey will end and will be directed to enter Dose 2 information.

Thank you for letting us know that you received your 2nd COVID-19 vaccine.

Please click the View My Account button below to view your account and register your 2nd COVID-19 vaccine.

For Johnson & Johnson and all 2 dose recipients who report 'No' above

Hi <name>.

Let's start today's health check-in .

How are you feeling today? 😊

☐ Good ☐ Fair ☐ Poor

Since your last check-in, have you experienced any new symptoms or worsening health conditions?

☐ Yes ☐ No

(if Yes) Please describe the symptoms or health conditions.

(if Yes) Did any of these symptoms or health conditions cause you to (check all that apply):

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) What type of healthcare visit did you have? (check all that apply)

- ☐ Telehealth, virtual health, or email health consultation
 - ☐ Outpatient clinic or urgent care clinic visit
 - ☐ Emergency room or emergency department visit
 - ☐ Hospitalization
 - ☐ Other, describe:
-

Since your last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

☐ Yes ☐ No

(if Yes) When were you diagnosed? _____(mm/dd/yyyy)_

Were you pregnant at the time of your COVID-19 vaccination?

(This is asked only for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)

☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

For Johnson & Johnson recipients:

Thanks for completing today's check-in.

Depending on your answers, CDC may call you to get more information about your symptoms. If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

We'll be in touch next week.

For Pfizer/Novovax/Moderna/AZ recipients who did not receive dose 2:

Thanks for completing today's check-in.

Depending on your answers, CDC may call you to get more information about your symptoms. It is time to get your 2nd COVID-19 vaccine. Please remember to make an appointment if you have not done so already!

After you receive your 2nd COVID-19 vaccination, please sign into your v-safe account and update your vaccination information.

If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

42 days (6 weeks) following COVID-19 vaccination:

Text message

Invitation: Hi <name>. It's time for your 6 week v-safe check-in. (*link to personalized survey*)

Reminder (sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey*)

Online survey from link in text message above

For all Moderna, AZ/ Pfizer/Novovax who did not previously report receipt of Dose 2:

Hi <name>.

Did you get your 2nd COVID-19 vaccination?

☐ Yes ☐ No

(If YES) Thank you.

Survey will end and will be directed to enter Dose 2 information

Thank you for letting us know that you received your 2nd COVID-19 vaccine.

Please click the View My Account button below to view your account and register your 2nd COVID-19 vaccine.

For Johnson & Johnson and all 2 dose recipients who report 'No' above

Hi <name>.

Let's start today's health check-in.

How are you feeling today? 😊

☐ Good ☐ Fair ☐ Poor

Since your last check-in, have you experienced any new symptoms or worsening health conditions?

☐ Yes ☐ No

(if Yes) Please describe the symptoms or health conditions.

(if Yes) Did any of these symptoms or health conditions cause you to (check all that apply):

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) What type of healthcare visit did you have? (check all that apply)

- ☐ Telehealth, virtual health, or email health consultation
- ☐ Outpatient clinic or urgent care clinic visit
- ☐ Emergency room or emergency department visit
- ☐ Hospitalization
- ☐ Other, describe:

Since your last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

☐ Yes ☐ No

(if Yes) When were you diagnosed? _____(mm/dd/yyyy)_

How would you describe your current state of health?

- ☐ Excellent
- ☐ Good
- ☐ Fair
- ☐ Poor

How is your health now compared to your health before your last COVID-19 vaccination?

- ☐ Better
- ☐ About the same
- ☐ Worse

(If Worse) Do you believe your health problems might be related to your COVID-19 vaccination?

- ☐ Yes
- ☐ No

Were you pregnant at the time of your COVID-19 vaccination?

(This is asked only for the initial survey taken for Dose 1; if this is the first survey then question below is not asked)

☐ Yes ☐ No ☐ Don't know

Since your last COVID-19 vaccination, have you had a home or laboratory pregnancy test that was positive?

(This is only asked if participant answered above pregnancy question in a previous survey)

- ☐ Yes
☐ No

Onscreen completion thank you message:

For all vaccine recipients at Day 42:

Thanks for completing today's check-in. Your contributions are helping CDC monitor the safety of COVID-19 vaccines.

Depending on your answers, CDC may call you to get more information about your symptoms.

If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

Take care and stay safe. We'll be in touch

V-safe Dose 2 surveys through Day 42:

Dose 2

Day 0 post vaccination

Text Message after + 2nd vaccine info completed

Hi <NAME>. It's time to check-in with v-safe for your 2nd vaccine dose. (*link to personalized v-safe survey*)

Online survey from link in text message above

Hi <name>.

Let's start today's health check-in.

How are you feeling today? 😊

☐ Good ☐ Fair ☐ Poor

Fever check

Since your second COVID-19 vaccination, have you had a fever or felt feverish?

☐ No ☐ Yes

(If Yes) Do you know your highest temperature reading from today?

- ☐ Yes- in degrees Fahrenheit
- ☐ Yes- in degrees Celsius
- ☐ No- I don't remember the reading
- ☐ No- I didn't take my temperature

Enter your highest temperature reading from today (degrees Fahrenheit)

Enter your highest temperature reading from today (degrees Celsius)

Symptom check

Symptoms can be classified as:

Mild = you notice symptoms, but they aren't a problem

Moderate = symptoms that limit of your normal daily activities

Severe = symptoms make normal daily activities difficult or impossible

Since your second COVID-19 vaccination, have you had any of these symptoms at or near the injection site?

Select all that apply: ☐ Pain ☐ Redness ☐ Swelling ☐ Itching

(If checked Pain) ☐ Mild ☐ Moderate ☐ Severe

(If checked Redness) ☐ Mild ☐ Moderate ☐ Severe

(If checked Swelling) ☐ Mild ☐ Moderate ☐ Severe

(If checked Itching) ☐ Mild ☐ Moderate ☐ Severe

Have you experienced any of these symptoms today?

Select all that apply.

- ☐ Chills
- ☐ Headache
- ☐ Joint pain
- ☐ Muscle or body aches
- ☐ Fatigue or tiredness
- ☐ Nausea
- ☐ Vomiting
- ☐ Diarrhea
- ☐ Abdominal pain
- ☐ Rash, not including the immediate area around the injection site
- ☐ None

Any other symptoms or health conditions you want to report _____

Medical symptoms can be classified as:

Mild = you notice symptoms, but they aren't a problem

Moderate = symptoms cause some limitation of your normal daily activities

Severe = symptoms make normal daily activities difficult or impossible"

(If checked Chills) ☐ Mild ☐ Moderate ☐ Severe

(If checked Headache) ☐ Mild ☐ Moderate ☐ Severe

(If checked Joint pain) ☐ Mild ☐ Moderate ☐ Severe

(If checked Muscle or body aches) ☐ Mild ☐ Moderate ☐ Severe

(If checked Fatigue or tiredness) ☐ Mild ☐ Moderate ☐ Severe

(If checked Nausea) ☐ Mild ☐ Moderate ☐ Severe

(If checked Vomiting) ☐ Mild ☐ Moderate ☐ Severe

(If checked Diarrhea) ☐ Mild ☐ Moderate ☐ Severe

(If checked Abdominal pain) ☐ Mild ☐ Moderate ☐ Severe

(If checked Rash, not including the immediate area around the injection site) ☐ Mild

☐ Moderate ☐ Severe

Health impact

Did any of the symptoms or health conditions you reported TODAY cause you to (Select all that apply):

- ☐ Be unable to work?
- ☐ Be unable to do your normal daily activities?
- ☐ Get care from a doctor or other healthcare professional?
- ☐ None of the above

(If “Get care...” checked) What type of healthcare visit did you have? (check all that apply)

- ☐ Telehealth, virtual health, or email health consultation
- ☐ Outpatient clinic or urgent care clinic visit
- ☐ Emergency room or emergency department visit
- ☐ Hospitalization
- ☐ Other, describe:

Were you pregnant at the time of your second COVID-19 vaccination? (*This is asked for the initial survey taken for Dose 2; if yes then no more pregnancy questions asked for Dose 2*)

☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

Thanks for completing today's check-in.

Depending on your answers, someone from CDC may call to check on you.

If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

We'll be in touch tomorrow.

Days 1-7 post vaccination

Text message & reminder:

Invitation text: Hi <name>. It's time for your daily v-safe check-in. (*link to personalized survey*)

Reminder text (only sent for Day 7 survey, 3 days after original text sent): Hi <name>. Please remember to do your daily v-safe check-in. (*link to personalized survey*)

Online survey from link in text message above

Hi <name>.

Let's start today's health check-in.

How are you feeling today? 😊

☐ Good ☐ Fair ☐ Poor

Fever check

Have you had a fever or felt feverish TODAY?

☐ No ☐ Yes

(If Yes) Do you know your highest temperature reading from today?

- ☐ Yes- in degrees Fahrenheit
- ☐ Yes- in degrees Celsius
- ☐ No- I don't remember the reading
- ☐ No- I didn't take my temperature

Enter your highest temperature reading from today (degrees Fahrenheit)

Enter your highest temperature reading from today (degrees Celsius)

Symptom check

Symptoms can be classified as:

Mild = you notice symptoms, but they aren't a problem

Moderate = symptoms that limit your normal daily activities

Severe = symptoms make normal daily activities difficult or impossible

Have you had any of these symptoms at or near the injection site today?

Check all that apply: ☐ Pain ☐ Redness ☐ Swelling ☐ Itching ☐ None

(If checked Pain) ☐ Mild ☐ Moderate ☐ Severe

(If checked Redness) ☐ Mild ☐ Moderate ☐ Severe

(If checked Swelling) ☐ Mild ☐ Moderate ☐ Severe

(If checked Itching) ☐ Mild ☐ Moderate ☐ Severe

Have you experienced any of these symptoms today?

Select all that apply:

- ☐ Chills
- ☐ Headache
- ☐ Joint pain
- ☐ Muscle or body aches
- ☐ Fatigue or tiredness
- ☐ Nausea
- ☐ Vomiting
- ☐ Diarrhea
- ☐ Abdominal pain
- ☐ Rash, not including the immediate area around the injection site
- ☐ None

Any other symptoms or health conditions you want to report _____

Medical symptoms can be classified as:

Mild = you notice symptoms, but they aren't a problem

Moderate = symptoms cause some limitation of your normal daily activities

Severe = symptoms make normal daily activities difficult or impossible"

(If checked Chills) ☐ Mild ☐ Moderate ☐ Severe

(If checked Headache) ☐ Mild ☐ Moderate ☐ Severe

(If checked Joint pain) ☐ Mild ☐ Moderate ☐ Severe

(If checked Muscle or body aches) ☐ Mild ☐ Moderate ☐ Severe

(If checked Fatigue or tiredness) ☐ Mild ☐ Moderate ☐ Severe

(If checked Nausea) ☐ Mild ☐ Moderate ☐ Severe

(If checked Vomiting) ☐ Mild ☐ Moderate ☐ Severe

(If checked Diarrhea) ☐ Mild ☐ Moderate ☐ Severe

(If checked Abdominal pain) ☐ Mild ☐ Moderate ☐ Severe

(If checked Rash, not including the immediate area around the injection site_ ☐ Mild
☐ Moderate ☐ Severe

Health impact

Did any of the symptoms or health conditions you reported today cause you to (Select all that apply):

- ☐ Be unable to work?
- ☐ Be unable to do your normal daily activities?
- ☐ Get care from a doctor or other healthcare professional?
- ☐ None of the above

(If "Get care..." checked) What type of healthcare visit did you have? (check all that apply)

- ☐ Telehealth, virtual health, or email health consultation
- ☐ Outpatient clinic or urgent care clinic visit
- ☐ Emergency room or emergency department visit

- ☐ Hospitalization
☐ Other, describe:
-

Were you pregnant at the time of your second COVID-19 vaccination? *(This is asked for the initial survey taken for Dose 2; if yes then no more pregnancy questions asked for Dose 2)*

☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

Thanks for completing today's check-in.

Depending on your answers, CDC may call you to get more information about your symptoms.

If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

We'll be in touch for your next check-in.

Weekly surveys: Days 14, 21, 28, 35– Dose 2

Text message and reminder:

Invitation: Hi <name>. It's time for your weekly v-safe check-in. (*link to personalized survey*)

Reminder(text sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey*)

Online survey from link in text message above

Hi <name>.

Let's start today's health check-in.

How are you feeling today? 😊

☐ Good ☐ Fair ☐ Poor

Since your last check-in, have you experienced any new symptoms or worsening health conditions?

☐ Yes ☐ No

(if Yes) Please describe the symptoms or health conditions:

(if Yes) “Did any of these symptoms or health conditions cause you to (check all that apply):”

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) “What type of healthcare visit did you have? (check all that apply)”

☐ Telehealth, virtual health, or email health consultation

☐ Outpatient clinic or urgent care clinic visit

☐ Emergency room or emergency department visit

☐ Hospitalization

☐ Other, describe:

Since your last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

☐ Yes ☐ No

(if Yes) When were you diagnosed? _____(mm/dd/yyyy)_

Were you pregnant at the time of your second COVID-19 vaccination? (*This is asked for the initial survey taken for Dose 2; if yes then no more pregnancy questions asked for Dose 2*)

☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

Thanks for completing today's check-in.

Depending on your answers, CDC may call you to get more information about your symptoms. If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

We'll be in touch next week.

42 days (6 weeks) following COVID-19 vaccination:

Text message

Invitation: Hi <name>. It's time for your 6 week v-safe check-in. (*link to personalized survey*)

Reminder (sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey*)

Online survey from link in text message above

Hi <name>.

Let's start today's health check-in.

How are you feeling today? 😊

☐ Good ☐ Fair ☐ Poor

Since your last check-in, have you experienced any new symptoms or worsening health conditions?

☐ Yes ☐ No

(if Yes) Please describe the symptoms or health conditions.

(if Yes) "Did any of these symptoms or health conditions cause you to (check all that apply):

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) What type of healthcare visit did you have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation

☐ Outpatient clinic or urgent care clinic visit

☐ Emergency room or emergency department visit

☐ Hospitalization

☐ Other, describe:

Since your last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

☐ Yes ☐ No

(if Yes) When were you diagnosed? _____(mm/dd/yyyy)_

How would you describe your current state of health?

- ☐ Excellent
☐ Good
☐ Fair
☐ Poor

How is your health now compared to your health before your last COVID-19 vaccination?

- ☐ Better
☐ About the same
☐ Worse

(If Worse) Do you believe your health problems might be related to your COVID-19 vaccination?

- ☐ Yes
☐ No

Were you pregnant at the time of your COVID-19 vaccination?

(This is only asked for the initial survey taken for Dose 2; if this is the first survey then question below is not asked)

☐ Yes ☐ No ☐ Don't know

Since your last COVID-19 vaccination, have you had a home or laboratory pregnancy test that was positive?

(This is only asked if participant answered above pregnancy question in a previous survey)

- ☐ Yes
☐ No

Onscreen completion thank you message:

Thanks for completing today's check-in. Your contributions are helping CDC monitor the safety of COVID-19 vaccines.

Depending on your answers, CDC may call you to get more information about your symptoms. If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

Take care and stay safe. We'll be in touch in a few months.

V-safe 3, 6 and 12 month surveys:

Monthly survey

Hi <name>.

Since we last contacted you, have you experienced any new symptoms or health conditions?

☐ Yes ☐ No

(if Yes) Please describe the symptoms or health conditions.

(if Yes) Did any of these symptoms or health conditions cause you to (check all that apply):

- ☐ Be unable to work?
- ☐ Be unable to do your normal daily activities?
- ☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?
- ☐ None of the above

(If Yes to got care [above]) What type of healthcare visit did you have? (check all that apply)

- ☐ Telehealth, virtual health, or email health consultation
- ☐ Outpatient clinic or urgent care clinic visit
- ☐ Emergency room or emergency department visit
- ☐ Hospitalization
- ☐ Other, describe:

Since your last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

☐ Yes ☐ No

(if Yes) When were you diagnosed? _____(mm/dd/yyyy)_

Since your last check-in, have you had a home or laboratory pregnancy test that was positive?

☐ Yes
☐ No

How would you describe your current state of health?

- ☐ Excellent
- ☐ Good
- ☐ Fair
- ☐ Poor

How is your health now compared to your health before your last COVID-19 vaccination?

- ☐ Better
- ☐ About the same
- ☐ Worse

(If Worse) Do you believe your health problems might be related to your COVID-19 vaccination?

- ☐ Yes
- ☐ No

Onscreen completion thank you message:

3/6 Month:

Thanks for completing today's check in. Your contributions are helping CDC monitor the safety of COVID-19 vaccines.

Depending on your answers, someone from CDC may call to check on you.

If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

Take care and stay safe.

12 Month:

Congratulations! You have completed your final v-safe check-in.

Depending on your answers, CDC may call you to get more information about your symptoms.

If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).

Thank you for participating in v-safe! Your contributions are helping CDC monitor the safety of COVID-19 vaccines.

Take care and stay safe.

Attachment 2: Adverse Events of Special Interest

Prespecified Medical Conditions
Acute myocardial infarction
Anaphylaxis
Coagulopathy
COVID-19 Disease
Death*
Guillain-Barré syndrome
Kawasaki disease
Multisystem Inflammatory Syndrome in children ¹
Multisystem Inflammatory Syndrome in adults ²
Myocarditis/Pericarditis
Narcolepsy/Cataplexy
Pregnancy and Prespecified Conditions
Seizures/Convulsions
Stroke
Transverse Myelitis

* Capture of deaths through v-safe will be limited.

Attachment 6



Office of the Secretary of State

CERTIFICATE OF FILING OF

Freedom Coalition of Doctors for Choice
File Number: 804899545

The undersigned, as Secretary of State of Texas, hereby certifies that a Certificate of Formation for the above named Domestic Nonprofit Corporation has been received in this office and has been found to conform to the applicable provisions of law.

ACCORDINGLY, the undersigned, as Secretary of State, and by virtue of the authority vested in the secretary by law, hereby issues this certificate evidencing filing effective on the date shown below.

The issuance of this certificate does not authorize the use of a name in this state in violation of the rights of another under the federal Trademark Act of 1946, the Texas trademark law, the Assumed Business or Professional Name Act, or the common law.

Dated: 01/26/2023

Effective: 01/26/2023



A handwritten signature in black ink that reads "Jane Nelson".

Jane Nelson
Secretary of State